

**OCCUPATIONAL SAFETY
AND HEALTH STANDARDS BOARD**

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NOTICE OF PROPOSED MODIFICATION TO
CALIFORNIA CODE OF REGULATIONS

TITLE 8: Chapter 4, Subchapter 7, Article 109, Section 5199
of the General Industry Safety Orders

Aerosol Transmissible Diseases

Pursuant to Government Code Section 11346.8(c), the Occupational Safety and Health Standards Board (Standards Board) gives notice of the opportunity to submit written comments on the above-named standards in which modifications are being considered as a result of public comments and/or Standards Board staff consideration.

On August 21, 2008, the Standards Board held a Public Hearing to consider revisions to Title 8, Section 5199 of the General Industry Safety Orders. The Standards Board received oral and written comments on the proposed revisions. The standards have been modified as a result of these comments and Standards Board consideration.

A copy of the pages with the modifications clearly indicated is attached for your information. In addition, a summary of all oral and written comments regarding the original proposal and staff responses is included.

Pursuant to Government Code Section 11346.8(d), notice is also given of the opportunity to submit comments concerning the addition to the rulemaking file of the following documents relied upon/incorporated by reference:

ADDITIONAL DOCUMENTS RELIED UPON

- Balazy A, Toivola M, Adhikari A, Sivasubramani K, Reponen T, and Grinshpun S. 2006. Do N95 respirators provide 95% protection level against airborne viruses, and how adequate are surgical masks? *Am J Infect Control* 34:51-57.
- Catanzaro A. Nosocomial Tuberculosis. *Am Rev Respir Dis*. 1982; 125:559-62.
- California Commission on Peace Officer Standards and Training. Model Respiratory Protection Program for Law Enforcement. May 2004.
- Coffey CC, et al. Fitting Characteristics of Eighteen N95 Filtering-Facepiece Respirators, *Journal of Occupational and Environmental Hygiene*, 1: 262-271, 2004.
- Duling, Matthew G. et al. Simulated Workplace Protection Factors for Half-Facepiece Respiratory Protective Devices. *Journal of Occupational and Environmental Hygiene*, 4:6, 420 - 431, 2007.
- Eninger RM, Honda T, Adhikari A, Heinonen-Tanski H, Reponen T, and Grinshpun S. 2008. Filter Performance of N99 and N95 Facepiece Respirators Against Viruses and Ultrafine Particles. *Ann Occup Hyg* 52:385-396.

- Fennelly, Kevin P. Transmission of Tuberculosis During Medical Procedures. *Clinical Infectious Diseases* 1997;25:1273-4.
- Fennelly, KP. The role of masks in preventing nosocomial transmission of tuberculosis. The International Journal of Tuberculosis and Lung Disease, Volume 2, Supplement 1, September 1998, pp. S103-S109(1).
- Fennelly, Kevin P. Cough-generated Aerosols of Mycobacterium tuberculosis A New Method to Study Infectiousness. *Am J Respir Crit Care Med* Vol 169. pp 604-609, 2004.
- Howard, John. Letter to Bill Borwegen and Bill Kojola dated July 9, 2007. (NIOSH Respirator Fit Test Letter).
- Iton, Anthony. Duties of the Local Health Officer. E-mail dated January 27, 2009.
- Johns Hopkins Safety Manual, Addendum A: Respiratory Protection Devices for Airborne Infectious Agents and Aerosolized Hazardous Drugs Protocol, 9/23/08.
- Lawrence RB et al. Comparison of Performance of Three Different Types of Respiratory Protection Devices. *Journal of Occupational and Environmental Hygiene*, 3: 465-474, September 2006.
- Lee K, Slavcev A, and Nicas M. 2004. Respiratory Protection Against Mycobacterium tuberculosis: Quantitative Fit Test Outcomes for Five Type N95 Filtering-Facepiece Respirators. *J Occup Environ Hyg* 1:22-28.
- Lee MC et al. Respirator-Fit Testing: Does It Ensure the Protection of Healthcare Workers Against Respirable Particles Carrying Pathogens? *Infection Control and Hospital Epidemiology*. December 2008, vol. 29, no. 12
- Lee, Shu-Ann et al. Respiratory Protection Provided by N95 Filtering Facepiece Respirators Against Airborne Dust and Microorganisms in Agricultural Farms. *Journal of Occupational and Environmental Hygiene*, 2: 577-585, 2005.
- Lee S, Grinshpun SA and Reponen T. Respiratory Performance Offered by N95 Respirators and Surgical Masks: Human Subject Evaluation with NaCl Aerosol Representing Bacterial and Viral Particle Size Range. *Ann Occup Hyg* 52:177-185, 2008.
- Loeb M et al. SARS among Critical Care Nurses, Toronto. *Emerging Infectious Diseases*, Vol. 10, No. 2, February 2004.
- Lucas A et al. Inadvertent Laboratory Exposure to *Bacillus anthracis* - California, 2004. *Morbidity and Mortality Weekly Report*, April 1, 2005 / 54(12);301-304.
- Mendelsohn, M. Letter to Deborah Gold dated September 29, 2008.
- Ofner M et al. Cluster of Severe Acute Respiratory Syndrome Cases Among Protected Health-Care Workers --- Toronto, Canada, April 2003. *Morbidity and Mortality Weekly Report (MMWR)*, May 16, 2003 / 52(19);433-436.
- Qian, Yingge et al. Performance of N95 Respirators: Filtration Efficiency for Airborne Microbial and Inert Particles. *American Industrial Hygiene Association Journal*; Feb 1998; 59, 2; ABI/INFORM Global pg. 128.
- Schulte P. Letter to Len Welsh dated October 15, 2008.
- Welsh, L. Letter to Paul Schulte dated August 28, 2008.

ADDITIONAL DOCUMENTS INCORPORATED BY REFERENCE

1. Epidemiology and Prevention of Vaccine-Preventable Diseases. Epidemiology and Prevention of Vaccine-Preventable Diseases. Centers for Disease Control and Prevention, Hamborsky J, McIntyre L, Wolfe S, eds. 10th ed. 2nd printing, including chapters from the 9th edition on Anthrax and Smallpox. Washington DC: Public Health Foundation, 2008, available at: <http://www.cdc.gov/vaccines/pubs/pinkbook/default.htm>
2. The following public health guidelines available at: <http://www.ctca.org/guidelines/index.html>
 - (A) Guidelines for Tuberculosis (TB) Screening and Treatment of Patients with Chronic Kidney Disease (CKD), Patients Receiving Hemodialysis (HD), Patients Receiving Peritoneal Dialysis (PD), Patients Undergoing Renal Transplantation and Employees of Dialysis Facilities, May 18, 2007.
 - (B) Guidelines for the Treatment of Active Tuberculosis Disease, April 15, 2003 (under review) including related material: Summary of Differences Between 2003 California and National Tuberculosis Treatment Guidelines, 2004, Amendment to Joint CDHS/CTCA Guidelines for the Treatment of Active Tuberculosis Disease, May 12, 2006, Appendix 3 - Algorithm for MDR-TB Cases and Hospital Discharge, May 12, 2006.
 - (C) Targeted Testing and Treatment of Latent Tuberculosis Infection in Adults and Children, May 12, 2006.
 - (D) California Tuberculosis Controllers Association Position Statement: The Utilization of QuantiFERON – TB Gold in California, May 18, 2007.
 - (E) Guidelines for Mycobacteriology Services in California, April 11, 1997.
 - (F) Guidelines for the Placement or Return of Tuberculosis Patients into High Risk Housing, Work, Correctional, or In-Patient Settings, April 11, 1997.
 - (G) Contact Investigation Guidelines, November 12, 1998.
 - (H) Source Case Investigation Guidelines, April 27, 2001.
 - (I) Guidelines on Prevention and Control of Tuberculosis in California Long-Term Health Care Facilities, October 2005.
 - (J) Guidelines for Reporting Tuberculosis Suspects and Cases in California, October 1997.
 - (K) CTCA recommendations for serial TB testing of Health Care Workers (CA Licensing and Certification), September 23, 2008.

These documents are too cumbersome or impractical to publish in Title 8. Therefore, it is proposed to incorporate the documents by reference. Copies of these documents are available for review during normal business hours at the Standards Board Office located at the address listed below.

Any written comments on these modifications must be received by 5:00 p.m. on March 15, 2009, at the Occupational Safety and Health Standards Board, 2520 Venture Oaks Way, Suite 350, Sacramento, California 95833. The standards will be scheduled for adoption at a future business meeting of the Standards Board.

The Standards Board's rulemaking files on the proposed action are open to public inspection Monday through Friday, from 8:00 a.m. to 4:30 p.m., at the Standards Board's office.

Inquiries concerning the proposed changes may be directed to the Executive Officer, Marley Hart, at (916) 274-5721.

OCCUPATIONAL SAFETY AND HEALTH
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Original signed by

Date: February 26, 2009

Marley Hart, Executive Officer

PROPOSED MODIFICATIONS
(Modifications are indicated in
underline wording for new language
and double strikeout for deleted language.)

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Add Section 5199 as follows:

§ 5199. ~~Melting Operations.~~ Aerosol Transmissible Diseases.

Contents

(a) Scope and Application

(b) Definitions

(c) Referring Employers

(d) Aerosol Transmissible Diseases Exposure Control Plan

(e) Engineering and Work Practice Controls and Personal Protective Equipment

(f) Laboratories

(g) Respiratory Protection

(h) Medical Surveillance Services

(i) Training

(j) Recordkeeping

(a) Scope and Application.

(1) Scope. This section applies to work in the following facilities, service categories, or operations:

(A) Each of the following health care facilities, services, or operations:

1. Hospitals
2. Skilled nursing facilities
3. Clinics, medical offices, and other outpatient medical facilities
4. Facilities where high hazard procedures, as defined in subsection (b) are performed
5. Home health care
- ~~6. Public health services~~
- ~~7. Long term health care facilities and hospices~~
- ~~8. Medical outreach services~~
- ~~9. Paramedic and emergency medical services including these services when provided by firefighters and other emergency responders~~
- ~~10. Medical transport~~

(B) Facilities, services, or operations that are designated to receive persons arriving from the scene of an uncontrolled release of hazardous substances involving biological agents, as defined in Section 5192, Hazardous Waste and Emergency Response Operations, of these orders.

(C) Police services, provided during transport or detention of persons when reasonably anticipated to be ~~provided to~~ cases or suspected cases of aerosol transmissible diseases; and police services provided in conjunction with health care or public health operations.

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(D) Public health services, such as communicable disease contact tracing or screening programs that are reasonably anticipated to be provided to cases or suspected cases of aerosol transmissible diseases, and public health services rendered in health care facilities or in connection with the provision of health care.

~~(DE)~~ The following facilities, services or operations that are identified as being at increased risk for transmission of aerosol transmissible disease (ATD) infection:

1. Correctional facilities and other facilities that house inmates or detainees
2. Homeless shelters
3. Drug treatment programs

~~(EF)~~ Facilities, services or operations that perform aerosol-generating procedures on cadavers such as pathology laboratories, medical examiners' facilities, coroners' offices, and mortuaries.

~~(EG)~~ Laboratories that perform procedures with materials that contain or are reasonably anticipated to contain aerosol transmissible pathogens – laboratory (ATP-L) or zoonotic aerosol transmissible pathogens as defined in Section 5199.1.

~~(EH)~~ Any other facility, service or operation that has been determined in writing by the Chief of the Division of Occupational Safety and Health through the issuance of an Order to Take Special Action, in accordance with Section 332.3 of these orders, to require application of this standard as a measure to protect employees.

~~(HI)~~ Maintenance, renovation, service, or repair operations involving air handling systems or equipment or building areas that may reasonably be anticipated to be contaminated with aerosol transmissible pathogens (ATPs) or ATPs-Ls, including:

1. Areas in which AirID cases and suspected cases are treated or housed.
2. Air handling systems that serve airborne infection isolation rooms or areas (AIIRs).
3. Equipment such as laboratory hoods, biosafety cabinets, and ventilation systems that are used to contain infectious aerosols.

NOTES to subsection (a)(1):

(1) Employers who conduct hazardous waste and emergency response operations, as defined in Section 5192 of these orders, shall also comply with the applicable requirements of Section 5192.

(2) Occupational exposure to animals infected by aerosol transmissible pathogens which cause human disease are regulated by Section 5199.1 of these orders.

(2) The following are not covered by this standard:

(A) Outpatient dental clinics or offices are not required to comply with this standard if they meet all of the following conditions:

~~€1).~~ Dental procedures are not performed on patients identified to them as ATD cases or suspected ATD cases.

~~€2).~~ ~~A-~~The Injury and Illness Prevention Program includes a written procedure for screening patients for ATDs that is consistent with current CDC guidelines for infection control in dental settings, and this procedure is followed before

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performing any dental procedure on a patient to determine whether the patient may present an ATD exposure risk.

3. Employees have been trained in the screening procedure in accordance with Section 3203.

~~(34). Aerosol generating dental procedures are not performed on a patient identified through the screening procedure as presenting a possible ATD exposure risk unless a licensed physician determines that the patient does not pose currently have an ATD risk to employees during the procedure.~~

(B) Outpatient medical specialty practices whose policy is not to diagnose or treat ATDs ~~are not required to comply with this standard if they meet all of the following conditions:~~
~~that~~

1. The medical specialty practice does not perform aerosol-generating procedures on cases or suspected cases of ATD;

2. The Injury and Illness Prevention Program includes ~~that have implemented~~ written screening procedures to identify potential ATD cases, and ~~that then~~ refer those patients for further evaluation to an appropriate medical provider;

3. Employees have been trained in the screening procedure in accordance with Section 3203.

(3) Application.

(A) Referring Employers. A referring employer is required only to comply with the provisions of subsection (a), subsection (c), including all parts of Section 5199 referred to in subsection (c), and subsection (j). To be a referring employer, the operation, service or facility must ~~do or not do~~ conform to each of the following, as indicated:

1. Screen persons for airborne infectious diseases (AirID).
2. Refer any person identified as a case or suspected case of AirID.
3. Not intend to provide further medical services to AirID cases and suspected cases beyond first aid, initial treatment or screening and referral as described in subsections (a)(3)(A)1 and (a)(3)(A)2 immediately above.
4. Not provide transport, housing, or airborne infection isolation (as defined in subsection (b)) to any person identified as an AirID case or suspected case, unless the transport provided is only non-medical transport in the course of a referral.

(B) Laboratories. A laboratory facility or operation in which employees do not have direct contact with cases or suspected cases of ATD or with potentially infected cadavers is required to comply only with the provisions of subsection (a), subsection (f), all provisions of Section 5199 referred to in subsection (f), subsection (i) and subsection (j).

(C) Work settings, operations, or facilities included within the scope of this standard that are not identified in subsections (a)(3)(A) or (a)(3)(B) shall comply with subsections (a), (d), (e), (f), (g), (h), (i), and (j).

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- (4) The employer shall provide all safeguards required by this section, including provision of personal protective equipment, respirators, training, and medical ~~surveillance services and management~~, at no cost to the employee, at a reasonable time and place for the employee, and during the employee's working hours.

(b) Definitions.

Accredited laboratory. A laboratory that is licensed by the CDPH pursuant to Title 17 of the California Code of Regulations (CCR), or which has participated in a quality assurance program leading to a certification of competence administered by a governmental or private organization that tests and certifies laboratories.

Aerosol transmissible disease (ATD) or aerosol transmissible pathogen (ATP). A disease or pathogen for which droplet or airborne precautions are ~~recommended~~required, as listed in Appendix A.

Aerosol transmissible pathogen -- laboratory (ATP-L). A pathogen that meets one of the following criteria: (1) the pathogen appears on the list in Appendix D, (2) the Biosafety in Microbiological and Biomedical Laboratories (BMBL) recommends biosafety level 3 or above for the pathogen, (3) the biological safety officer recommends biosafety level 3 or above for the pathogen, or (4) the pathogen is a novel or unknown pathogen.

Airborne infection isolation (AII). Infection control procedures as described in Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings. These procedures are designed to reduce the risk of transmission of airborne infectious pathogens, and apply to patients known or suspected to be infected with epidemiologically important pathogens that can be transmitted by the airborne route.

Airborne infection isolation room or area (AIIR). A room, area, booth, tent, or other enclosure that is maintained at negative pressure to adjacent areas in order to control the spread of aerosolized *M. tuberculosis* and other airborne infectious pathogens and that meets the requirements stated in subsection (e)(5)(D) of this standard.

Airborne infectious disease (AirID). Either: (1) an aerosol transmissible disease transmitted through dissemination of airborne droplet nuclei, small particle aerosols, or dust particles containing the disease agent for which AII is recommended by the CDC or CDPH, as listed in Appendix A, or (2) the disease process caused by a novel or unknown pathogen for which there is no evidence to rule out with reasonable certainty the possibility that the pathogen is transmissible through dissemination of airborne droplet nuclei, small particle aerosols, or dust particles containing the novel or unknown pathogen.

Airborne infectious pathogen (AirIP). Either: (1) an aerosol transmissible pathogen transmitted through dissemination of airborne droplet nuclei, small particle aerosols, or dust particles containing the infectious agent, and for which the CDC or CDPH recommends AII, as listed in Appendix A, or (2) a novel or unknown pathogen for which there is no evidence to rule out with reasonable certainty the possibility that it is transmissible through dissemination of airborne droplet nuclei, small particle aerosols, or dust particles containing the novel or unknown pathogen.

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Biosafety level 3. Compliance with the criteria for laboratory practices, safety equipment, and facility design and construction recommended by the CDC in Biosafety in Microbiological and Biomedical Laboratories for laboratories in which work is done with indigenous or exotic agents with a potential for aerosol transmission and which may cause serious or potentially lethal infection.

Biosafety in Microbiological and Biomedical Laboratories (BMBL). Biosafety in Microbiological and Biomedical Laboratories, Fifth Edition, CDC and National Institutes for Health, 2007, which is hereby incorporated by reference for the purpose of establishing biosafety requirements in laboratories.

Biological safety officer(s). A person who is qualified by training and/or experience to evaluate hazards associated with laboratory procedures involving ATP_S-L, who is knowledgeable about the facility biosafety plan, and who is authorized by the employer to establish and implement effective control measures for laboratory biological hazards.

CDC. United States Centers for Disease Control and Prevention.

CDPH. California Department of Public Health and its predecessor, the California Department of Health Services (CDHS).

Case. Either of the following:

(~~A~~1) A person who has been diagnosed by a health care provider who is lawfully authorized to diagnose, using clinical judgment or laboratory evidence, to have a particular disease or condition. ~~or~~

(~~B~~2) A person who is considered a case of a disease or condition that satisfies the most recent communicable disease surveillance case definitions established by the CDC and published in the Morbidity and Mortality Weekly Report (MMWR) or its supplements.

Chief. The Chief of the Division of Occupational Safety and Health of the Department of Industrial Relations, or his or her designated representative.

CTCA. The California Tuberculosis Controllers Association.

Droplet precautions. Infection control procedures as described in Guideline for Isolation Precautions designed to reduce the risk of transmission of infectious agents through contact of the conjunctivae or the mucous membranes of the nose or mouth of a susceptible person with large-particle droplets (larger than 5 µm in size) containing microorganisms generated from a person who has a clinical disease or who is a carrier of the microorganism.

Drug treatment program. A program that is (A) licensed pursuant to Chapter 7.5 (commencing with Section 11834.01), Part 2, Division 10.5 of the Health and Safety Code; or Chapter 1 (commencing with Section 11876), Part 3, Article 3, Division 10.5 of the Health and Safety Code; or (B) certified as a substance abuse clinic or satellite clinic pursuant to Section 51200, Title 22, CCR, and which has submitted claims for Medi-Cal reimbursement pursuant to Section 51409.1, Title 22, CCR, within the last two calendar years or (C) certified pursuant to Section 11831.5 or Section 11994 of the Health and Safety Code.

Emergency medical services. Medical care provided pursuant to Title 22, Division 9, by employees who are certified EMT-I, certified EMT-II, or licensed paramedic personnel to the sick and injured at the scene of an emergency, during transport, or during interfacility transfer.

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Epidemiology and Prevention of Vaccine-Preventable Diseases. Epidemiology and Prevention of Vaccine-Preventable Diseases. Centers for Disease Control and Prevention, Atkinson W, Hamborsky J, McIntyre L, Wolfe S, eds. 10th ed. 2nd printing, including chapters from the 9th edition on Anthrax and Smallpox, Washington DC: Public Health Foundation, 2008, available at: <http://www.cdc.gov/vaccines/pubs/pinkbook/default.htm>, which is hereby incorporated by reference.

Exposure incident. An event in which all of the following have occurred: (1) ~~a~~An employee has been exposed to an individual who is a case or suspected case of a reportable ATD, or to a work area or to equipment that is reasonably expected to contain ATPs associated with a reportable ATD; and (2) ~~†~~The exposure occurred without the benefit of applicable exposure controls required by this section, and (3) ~~†~~It reasonably appears from the circumstances of the exposure that transmission of disease is sufficiently likely to require medical evaluation.

Exposure incident (laboratory). A significant exposure to an aerosol containing an ATP-L, without the benefit of applicable exposure control measures required by this section.

Field operation. An operation conducted by employees that is outside of the employer's fixed establishment, such as paramedic and emergency medical services or transport, law enforcement, home health care, and public health.

Guideline for Isolation Precautions. ~~means †~~The Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings, June 2007, CDC, which is hereby incorporated by reference for the sole purpose of establishing requirements for droplet and contact precautions.

Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings. ~~means †~~The Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings, December 2005, CDC, which is hereby incorporated by reference for the sole purpose of establishing requirements for airborne infection isolation.

Health care provider. A physician and surgeon, a veterinarian, a podiatrist, a nurse practitioner, a physician assistant, a registered nurse, a nurse midwife, a school nurse, an infection control practitioner, a medical examiner, a coroner, or a dentist.

Health care worker. A person who works in a health care facility, service or operation, or who has occupational exposure in a public health service described in subsection (a)(1)(D).

High hazard procedures. Procedures performed on a person who is a case or suspected case of an aerosol transmissible disease or on a specimen suspected of containing an ATP-L, in which the potential for being exposed to aerosol transmissible pathogens is increased due to the reasonably anticipated generation of aerosolized pathogens. Such procedures include, but are not limited to, sputum induction, bronchoscopy, aerosolized administration of pentamidine or other medications, and pulmonary function testing. High Hazard Procedures also include, but are not limited to, autopsy, clinical, surgical and laboratory procedures that may aerosolize pathogens.

Individually identifiable medical information. ~~means †~~Medical information that includes or contains any element of personal identifying information sufficient to allow identification of the individual, such as the patient's name, address, electronic mail address, telephone number, or

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social security number, or other information that, alone or in combination with other publicly available information, reveals the individual's identity.

Infection control PLHCP. A PLHCP who is knowledgeable about infection control practices, including routes of transmission, isolation precautions and the investigation of exposure incidents.

Initial treatment. Treatment provided at the time of the first contact a health care provider has with a person who is potentially an AirID case or suspected case. Initial treatment does not include high hazard procedures.

Laboratory. A facility or operation in a facility where the manipulation of specimens or microorganisms is performed for the purpose of diagnosing disease or identifying disease agents, conducting research or experimentation on microorganisms, replicating microorganisms for distribution or related support activities for these processes.

Latent TB infection (LTBI). Infection with *M. tuberculosis* in which bacteria are present in the body, but are inactive. Persons who have LTBI but who do not have TB disease are asymptomatic, do not feel sick and cannot spread TB to other persons. They typically react positively to TB tests.

Local health officer. The health officer for the local jurisdiction responsible for receiving and/or sending reports of communicable diseases, as defined in Title 17, CCR.

NOTE: Title 17, Section 2500 requires that reports be made to the local health officer for the jurisdiction where the patient resides.

M. tuberculosis. ~~means~~ *Mycobacterium tuberculosis* complex, which includes *M. tuberculosis*, *M. bovis*, *M. africanum*, and *M. microti*. *M. tuberculosis* is ~~the~~ The scientific name of the group of ~~bacterium~~ bacteria that causes tuberculosis.

Medical specialty practice. A medical practice other than primary care, general practice, or family medicine.

Negative pressure. ~~A~~ The relative air pressure difference between two areas. The pressure in a containment room or area that is under negative pressure is lower than adjacent areas, which keeps air from flowing out of the containment facility and into adjacent rooms or areas.

NIOSH. The Director of the National Institute for Occupational Safety and Health, CDC, or his or her designated representative.

Non-medical transport. The transportation by employees other than health care providers or emergency medical personnel during which no medical services are reasonably anticipated to be provided.

Novel or unknown ATP. A pathogen capable of causing serious human disease meeting the following criteria:

- (1) There is credible evidence that the pathogen is transmissible to humans by aerosols; and
- (2) The disease agent is:
 - (a) A newly recognized pathogen, or

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(b) A newly recognized variant of a known pathogen and there is reason to believe that the variant differs significantly from the known pathogen in virulence or transmissibility, or

(c) A recognized pathogen that has been recently introduced into the human population, or

(d) A not yet identified pathogen.

NOTE: Variants of the human influenza virus that typically occur from season to season are not considered novel or unknown ATPs if they do not differ significantly in virulence or transmissibility from existing seasonal variants. Pandemic influenza strains that have not been fully characterized are novel pathogens.

Occupational exposure. Exposure from work activity or working conditions that is reasonably anticipated to create an elevated risk of contracting any disease caused by ATPs or ATPs-L* if protective measures are not in place. In this context, “elevated” means higher than what is considered ordinary for employees having direct contact with the general public outside of the facilities, service categories and operations listed in subsection (a)(1) of this standard.

Occupational exposure is presumed to exist to some extent in each of the facilities, services and operations listed in subsection (a)(1)(A) through (a)(1)(~~H~~). Whether a particular employee has occupational exposure depends on the tasks, activities, and environment of the employee, and therefore, some employees of a covered employer may have no occupational exposure. For example, occupational exposure typically does not exist where a hospital employee works only in an office environment separated from patient care facilities, or works only in other areas separate from those where the risk of ATD transmission, whether from patients or contaminated items, would be elevated without protective measures. It is the task of employers covered by this standard to identify those employees who have occupational exposure so that appropriate protective measures can be implemented to protect them as required. Employee activities that involve having contact with, or being within exposure range of cases or suspected cases of ATD, are always considered to cause occupational exposure. Similarly, employee activities that involve contact with, or routinely being within exposure range of, ~~at-risk~~ populations served by facilities identified in subsection (a)(1)(E) are considered to cause occupational exposure. Employees working in laboratory areas in which ATPs-L are handled or reasonably anticipated to be present are also considered to have occupational exposure.

Physician or other licensed health care professional (PLHCP) means an individual whose legally permitted scope or practice (i.e., license, registration, or certification) allows him or her to independently provide, or be delegated the responsibility to provide, some or all of the health care services required by this section.

Public health guidelines. (1) In regards to tuberculosis, applicable guidelines published by the CTCA and/or CDPH as follows, which are hereby incorporated by reference:

(A) Guidelines for Tuberculosis (TB) Screening and Treatment of Patients with Chronic Kidney Disease (CKD), Patients Receiving Hemodialysis (HD), Patients Receiving Peritoneal Dialysis (PD), Patients Undergoing Renal Transplantation and Employees of Dialysis Facilities, May 18, 2007.

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(B) Guidelines for the Treatment of Active Tuberculosis Disease, April 15, 2003 including related material: Summary of Differences Between 2003 California and National Tuberculosis Treatment Guidelines, 2004, Amendment to Joint CDHS/CTCA Guidelines for the Treatment of Active Tuberculosis Disease, May 12, 2006, Appendix 3 - Algorithm for MDR-TB Cases and Hospital Discharge, May 12, 2006.

(C) Targeted Testing and Treatment of Latent Tuberculosis Infection in Adults and Children, May 12, 2006.

(D) California Tuberculosis Controllers Association Position Statement: The Utilization of QuantiFERON – TB Gold in California, May 18, 2007.

(E) Guidelines for Mycobacteriology Services in California, April 11, 1997.

(F) Guidelines for the Placement or Return of Tuberculosis Patients into High Risk Housing, Work, Correctional, or In-Patient Settings, April 11, 1997.

(G) Contact Investigation Guidelines, November 12, 1998.

(H) Source Case Investigation Guidelines, April 27, 2001.

(I) Guidelines on Prevention and Control of Tuberculosis in California Long-Term Health Care Facilities, October 2005.

(J) Guidelines for Reporting Tuberculosis Suspects and Cases in California, October 1997.

(K) CTCA recommendations for serial TB testing of Health Care Workers (CA Licensing and Certification), September 23, 2008.

(2) In regards to vaccine-preventable diseases, the publication cited in the definition of Epidemiology and Prevention of Vaccine-Preventable Diseases.

(3) In regards to any disease or condition not addressed by the above guidelines, recommendations made by the CDPH or the local health officer pursuant to authority granted under the Health and Safety Code and/or Title 17, California Code of Regulations.

Referral. The directing or transferring of a possible ATD case to another facility, service or operation for the purposes of transport, diagnosis, treatment, isolation, housing or care.

Referring employer. Any employer that operates a facility, service, or operation in which there is occupational exposure and which refers AirID cases and suspected cases to other facilities. Referring facilities, services and operations do not provide diagnosis, treatment, transport, housing, isolation or management to persons requiring AII. General acute care hospitals are not referring employers. Law enforcement, corrections, public health, and other operations that provide only non-medical transport for referred cases are considered referring employers if they do not provide diagnosis, treatment, housing, isolation or management of referred cases.

Reportable aerosol transmissible disease (RATD). ~~An aerosol transmissible disease or condition which a health care provider is required to report to the local health officer, in accordance with Title 17 CCR, Chapter 4, and which meets the definition of an aerosol transmissible disease (ATD). for which the CDC or the CDPH recommend droplet precautions or AII.~~

Respirator. A device which has met the requirements of 42 CFR Part 84, has been designed to protect the wearer from inhalation of harmful atmospheres, and has been approved by NIOSH. for the purpose for which it is used.

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Respirator user. An employee who in the scope of their current job may be assigned to tasks which may require the use of a respirator, in accordance with subsection (g).

Respiratory Hygiene/Cough Etiquette in Health Care Settings. Respiratory Hygiene/Cough Etiquette in Health Care Settings, CDC, November 4, 2004, which is hereby incorporated by reference for the sole purpose of establishing requirements for source control procedures

Screening (health care provider). The initial assessment of persons who are potentially AirID or ATD cases by a health care provider in order to determine whether they need airborne infection isolation or need to be referred for further medical evaluation or treatment to make that determination. Screening does not include ~~diagnostic testing~~ high hazard procedures.

Screening (non health care provider). The identification of potential ATD cases through readily observable signs and the self-report of patients or clients. Screening does not include ~~diagnostic testing~~ high hazard procedures.

Significant exposure. An exposure to a source of ATPs or ATPs-L in which the circumstances of the exposure make the transmission of a disease sufficiently likely that the employee requires further evaluation by a PLHCP.

Source control measures. The use of procedures, engineering controls, and other devices or materials to minimize the spread of airborne particles and droplets from an individual who has or exhibits signs or symptoms of having an ATD, such as persistent coughing.

Surge. A rapid expansion beyond normal services to meet the increased demand for qualified personnel, medical care, equipment, and public health services in the event of an epidemic, public health emergency, or disaster.

Susceptible person. A person who is at risk of acquiring an infection due to a lack of immunity as determined by a PLHCP in accordance with ~~current applicable CDC or CDPH~~ public health guidelines.

Suspected case. Either of the following:

(1) A person whom a health care provider believes, after weighing signs, symptoms, and/or laboratory evidence, to probably have a particular disease or condition listed in Appendix A.

(2) A person who is considered a probable case, or an epidemiologically-linked case, or who has supportive laboratory findings under the most recent communicable disease surveillance case definition established by CDC and published in the Morbidity and Mortality Weekly Report (MMWR) or its supplements as applied to a particular disease or condition listed in Appendix A.

TB conversion. A change from negative to positive as indicated by TB test results, based upon current CDC or CDPH guidelines for interpretation of the TB test.

Test for tuberculosis infection (TB test). Any test, including the tuberculin skin test and blood assays for *M. Tuberculosis* (BAMT) such as interferon gamma release assays (IGRAs) which:

(1) has been approved by the Food and Drug Administration for the purposes of detecting tuberculosis infection, and (2) is recommended by the CDC for testing for TB infection in the environment in which it is used, and (3) is administered, performed, analyzed and evaluated in accordance with those approvals and guidelines.

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NOTE: Where surveillance for LTBI is required by Title 22, CCR, the TB test must be approved for this use by the CDPH.

Tuberculosis (TB). A disease caused by *M. tuberculosis*.

UVGI. Ultraviolet germicidal irradiation.

(c) Referring Employers. In facilities, services, or operations in which there is occupational exposure and which meet the criteria specified by (a)(3)(A), employers are only required to comply with the following provisions:

- (1) The employer shall designate a person as the administrator who will be responsible for the establishment, implementation and maintenance of effective written infection control procedures to control the risk of transmission of aerosol transmissible diseases. The administrator shall have the authority to perform this function and shall be knowledgeable in infection control principles as they apply specifically to the facility, service or operation. The administrator shall also identify in writing the job categories in which employees have occupational exposure to ATDs. When the administrator is not on site, there shall be a designated person with full authority to act on his or her behalf. The infection control procedures shall include procedures for the cleaning and disinfection of work areas, vehicles, and equipment that may become contaminated with ATPs and pose an infection risk to employees. The written procedures shall be available at the worksite.
- (2) The employer shall establish, implement, and maintain effective written source control procedures. For fixed health care and correctional facilities, and in other facilities, services, and operations to the extent reasonably practicable, these procedures shall incorporate the recommendations contained in the Respiratory Hygiene/Cough Etiquette in Health Care Settings. These procedures shall include the method of informing persons with whom employees will have contact of the employer's source control measures.
- (3) The employer shall establish, implement, and maintain effective written procedures for the screening and referral of cases and suspected cases of AirIDs to appropriate facilities.
 - (A) Transfers shall occur within 5 hours of the identification of the case or suspected case, unless:
 - (1) the initial encounter with the case or suspected case occurs after 3:30 p.m. and prior to 7 a.m., in which event the employer shall ensure that transfer occurs no later than 11:00 a.m.; or
 - (2) the employer has contacted the local health officer, determined that there is no facility that can provide appropriate AII, and complied with all of the conditions in (e)(5)(B)2.; or
 - (3) the case meets the conditions of either of the exceptions to subsection (e)(5)(B)2.
 - (B) When screening is provided by persons who are not health care providers, the employer shall meet the requirements of this section by establishing criteria and procedures for referral of persons to a health care provider for further evaluation within the timeframes in subsection (c)(3)(A). Referrals shall be provided to persons who do any of the following:

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1. Have a ~~persistent~~ cough for more than three weeks that is not explained by non-infectious conditions.
2. Exhibit signs and symptoms of a flu-like illness during March through October, the months outside of the typical period for seasonal influenza, or exhibit these signs and symptoms for a period longer than two weeks at any time during the year. ~~‡~~ These signs and symptoms generally include combinations of the following: coughing and other respiratory symptoms, fever, sweating, chills, muscle aches, weakness and malaise.
3. State that they have a transmissible respiratory disease, excluding the common cold and seasonal influenza.
4. State that they have been exposed to an infectious ATD case, other than seasonal influenza.

NOTES to subsection (c)(3):

1. Seasonal influenza does not require referral.
 2. Appendix F contains ~~a sample procedure~~ criteria for screening that may be adopted by employers in non-medical settings for the purpose of meeting the requirements of this subsection.
- (4) The employer shall establish, implement, and maintain effective written procedures to communicate with employees, ~~and other employers,~~ and the local health officer regarding the suspected or diagnosed infectious disease status of referred patients. These shall include procedures to receive information from the facility to which patients were referred and to provide necessary infection control information to employees who were exposed to the referred person.
- (5) The employer shall establish, implement and maintain effective written procedures to reduce the risk of transmission of aerosol transmissible disease, to the extent feasible, during the period the person requiring referral is in the facility or is in contact with employees. In addition to source control measures, these procedures shall include, to the extent feasible:
- (A) placement of the person requiring referral in a separate room or area;
 - (B) provision of separate ventilation or filtration in the room or area; and
 - (C) employee use of respiratory protection when entering the room or area in which the person requiring referral is located, if that person is not compliant with source control measures. Respirator use shall meet the requirements of subsection (g) and Section 5144, Respiratory Protection, of these orders.
- EXCEPTION to subsection (c)(5)(C): Law enforcement or corrections personnel who transport a person requiring referral in a vehicle need not use respiratory protection if all of the following conditions are met:
- i. A solid partition separates the passenger area from the area where employees are located;
 - ii. The ~~employer's~~ employer implements written procedures that specify the conditions of operation, including the condition of windows and fans;

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- iii. The employer tests (e.g., by the use of smoke tubes) the airflow in a representative vehicle (of the same model, year of manufacture, and partition design) under the specified conditions of operation, and finds that there is no detectable airflow from the passenger compartment to the employee area;
 - iv. The employer records the results of the tests and maintains the results in accordance with subsection (j)(3)(~~FE~~); and
 - v. The person performing the test is knowledgeable about the assessment of ventilation systems.
- (6) The employer shall establish a system of medical ~~surveillance~~ services for employees which meets the following requirements:
- (A) The employer shall make available to all health care workers with occupational exposure all vaccinations recommended by the CDPH as listed in Appendix E in accordance with subsection (h). These vaccinations shall be provided by a PLHCP at a reasonable time and place for the employee.
 - (B) The employer shall develop, implement, and maintain effective written procedures for exposure incidents in accordance with subsections (h)(6) through (h)(9).
 - (C) The employer shall establish, implement, and maintain an effective surveillance program for LTBI in accordance with subsections (h)(3) and (h)(4).
 - (D) The employer shall establish, implement, and maintain effective procedures for providing vaccinations against seasonal influenza to all employees with occupational exposure, in accordance with subsection (h)(10).
EXCEPTION to subsection (c)(6)(D): Seasonal influenza vaccine shall be provided during the period designated by the CDC for administration and need not be provided outside of those periods.
- (7) Employers shall ensure that all employees with occupational exposure participate in a training program. Training shall be provided at the time of initial assignment to tasks where occupational exposure may take place and at least annually thereafter. Additional training shall be provided when there are changes in the workplace or when there are changes in procedures that could affect worker exposure to ATPs. The person conducting the training shall be knowledgeable in the subject matter covered by the training program as it relates to the workplace. Training material appropriate in content and vocabulary to the educational level, literacy, and language of employees shall be used. This training shall include:
- (A) A general explanation of ATDs including the signs and symptoms that require further medical evaluation;
 - (B) Screening methods and criteria for persons who require referral;
 - (C) The employer's source control measures and how these measures will be communicated to persons the employees contact;
 - (D) The employer's procedures for making referrals in accordance with subsection (c)(3);

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- (E) The employer's procedures for temporary risk reduction measures prior to transfer;
 - (F) Training in accordance with subsection (g) and Section 5144 of these orders, when respiratory protection is used;
 - (G) The employer's medical ~~surveillance~~ services procedures in accordance with subsection (h), ~~and the methods of reporting exposure incidents, and the employer's procedures for providing employees with post-exposure evaluation;~~
 - (H) Information on vaccines the employer will make available, including the seasonal influenza vaccine. For each vaccine, this information shall include the efficacy, safety, method of administration, the benefits of being vaccinated, and that the vaccine and vaccination will be offered free of charge;
 - (I) How employees can access the employer's written procedures and how employees can participate in reviewing the effectiveness of the employer's procedures in accordance with subsection (c)(8); and
 - (J) An opportunity for interactive questions and answers with a person who is knowledgeable in the subject matter as it relates to the workplace that the training addresses and who is also knowledgeable in the employer's infection control procedures. Training not given in person shall provide for interactive questions to be answered within 24 hours by a knowledgeable person. ~~the person conducting the training.~~
- (8) The employer shall ensure that the infection control procedures are reviewed at least annually by the administrator and by employees regarding the effectiveness of the program with the employees in their respective work areas, and that deficiencies found are corrected.
- (9) The employer shall establish and maintain training records, vaccination records, records of exposure incidents, and records of inspection, testing, and maintenance of non-disposable engineering controls, in accordance with subsection (j). If the employer utilizes respirators, the employer shall maintain records of implementation of the Respiratory Protection Program in accordance with Section 5144, Respiratory Protection, of these orders.
- (d) Aerosol Transmissible Diseases Exposure Control Plan.**
- (1) The employer shall establish, implement, and maintain an effective, written ATD Exposure Control Plan (Plan) which is specific to the work place or operation(s), and which contains all of the elements in subsection (d)(2).
EXCEPTION to subsection (d)(1): Employers with laboratory operations in which employees do not have direct patient contact may establish, implement and maintain an effective, written Biosafety Plan meeting the requirements of subsection (f) in lieu of an Exposure Control Plan for those operations.
 - (2) The Plan shall contain all of the following elements:

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- (A) The name(s) or title(s) of the person(s) responsible for administering the Plan.
This person shall be knowledgeable in infection control principles and practices as they apply to the facility, service or operation.
- (B) list of all job classifications in which employees have occupational exposure.
- (C) A list of all high hazard procedures performed in the facility, service or operation, and the job classifications and operations in which employees are exposed to those procedures.
- (D) A list of all assignments or tasks requiring personal or respiratory protection.
- (E) The methods of implementation of subsections (e), (g), (h), (i) and (j) as they apply to that facility, service or work operation. Specific control measures shall be listed for each ~~type or group of tasks, operations, or work areas~~ in which occupational exposures occurs. These measures shall include applicable engineering and work practice controls, cleaning and decontamination procedures, and personal protective equipment and respiratory protection. In establishments where the Plan pertains to laboratory operations, it also shall contain the methods of implementation for subsection (f), unless those operations are included in a Biosafety Plan.
- ~~(F) Surge procedures. Employers of employees who are designated to provide services in surge conditions, and employers of employees who are designated to provide services to persons who have been contaminated as the result of a release of a biological agent, shall establish and implement work practices and procedures for such events, including patient isolation, the provision of decontamination facilities, and appropriate personal protective equipment and respiratory protection for such events.~~
- ~~(G)~~ (F) A description of the source control measures to be implemented in the facility, service or operation, and the method of informing people entering the work setting of the source control measures.
- ~~(H)~~ (G) The procedures the employer will use to identify, temporarily isolate, and refer or transfer AirID cases or suspected cases to AII rooms, areas or facilities. These procedures shall include the methods the employer will use to limit employee exposure to these persons during periods when they are not in airborne infection isolation rooms or areas. These procedures shall also include the methods the employer will use to document medical decisions not to transfer patients in need of AII in accordance with subsection (e)(5)(B)2.
- ~~(H)~~ (H) The procedures the employer will use to provide medical surveillance services, including recommended vaccinations and follow-up, as required in subsection (h). This shall include the procedures the employer will use to document the lack of availability of a recommended vaccine.
- ~~(I)~~ (I) The procedures for employees and supervisors to follow in the event of an exposure incident, including how the employer will determine which employees had a significant exposure, in accordance with subsections (h)(6) through (h)(9).

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- ~~(K)~~ (J) The procedures the employer will use to evaluate each exposure incident, to determine the cause, and to revise existing procedures to prevent future incidents.
- ~~(L)~~ (K) The procedures the employer will use to communicate with its employees and other employers regarding the suspected or confirmed infectious disease status of persons to whom employees are exposed in the course of their duties, in accordance with subsection (h).
- ~~(M)~~ (L) The procedures the employer will use to communicate with other employers regarding exposure incidents, including procedures for providing or receiving notification to and from health care providers about the disease status of referred or transferred patients, in accordance with subsection (h).
- ~~(N)~~ (M) The procedures the employer will use to ensure that there is an adequate supply of personal protective equipment and other equipment necessary to minimize employee exposure to ATPs, in normal operations, and in foreseeable emergencies, and surge situations.
- ~~(O)~~ (N) The procedures the employer will use to provide initial and annual training in accordance with subsection (i) to employees in job categories identified in subsection (d)(2)(B).
- ~~(P)~~ (O) The procedures the employer will use for recordkeeping, in accordance with subsection (j).
- ~~(Q)~~ (P) ~~The procedures the employer will use to involve employees in the review of the ATD Plan.~~ An effective procedure for obtaining the active involvement of employees in reviewing and updating the exposure control plan with respect to the procedures performed in their respective work areas or departments in accordance with subsection (d)(3).
- (Q) Surge procedures. Employers of employees who are designated to provide services in surge conditions, and employers of employees who are designated to provide services to persons who have been contaminated as the result of a release of a biological agent as described in subsection (a)(1)(B), shall include procedures for these activities in the plan. The plan shall include work practices, decontamination facilities, and appropriate personal protective equipment and respiratory protection for such events. The procedures shall include how respiratory and personal protective equipment will be stockpiled, accessed or procured, and how the facility or operation will interact with the local and regional emergency plan.
- (3) The ATD Plan shall be reviewed at least annually by the program administrator, and by employees regarding the effectiveness of the program in their respective work areas. Deficiencies found shall be corrected. The review(s) shall be documented in writing, in accordance with subsection (j)(3)(A).
- (4) The Plan shall be made available to employees, employee representatives, the Chief and NIOSH for examination and copying, in accordance with subsection (j)(4).

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(e) Engineering and Work Practice Controls, and Personal Protective Equipment.

(1) General. Employers shall use feasible engineering and work practice controls to minimize

employee exposures to ATPs. Where engineering and work practice controls do not provide sufficient protection (e.g., when an employee enters an AII room or area) the employer shall provide, and ensure that employees use, personal protective equipment, and shall provide respiratory protection in accordance with subsection (g) to control exposures to AirIPs.

(A) Work practices shall be implemented to prevent or minimize employee exposures to airborne, droplet, and contact transmission of aerosol transmissible pathogens (ATP), in accordance with Appendix A, and where not addressed by Appendix A, in accordance with the Guideline for Isolation Precautions. Droplet and contact precautions shall be in accordance with Guideline for Isolation Precautions. Airborne precautions shall be in accordance with Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings.

NOTE: These work practices may include, but are not limited to; handwashing and gloving procedures; the use of anterooms; ~~the use of respiratory protection; the use of personal protective equipment such as eye and face protection, surgical masks, gowns and other protective apparel;~~ and cleaning and disinfecting contaminated surfaces, articles and linens.

(B) Each employer shall implement written source control procedures. For fixed health care and correctional facilities, and in field operations to the extent that it is reasonably practicable, these procedures shall incorporate the recommendations contained in the Respiratory Hygiene/Cough Etiquette in Health Care Settings. The procedures shall include methods to inform individuals entering the facility, being transported by employees, or otherwise in close contact with employees, of the source control practices implemented by the employer.

(C) Employers shall develop and implement engineering and work practice controls to protect employees who operate, use, or maintain vehicles that transport persons who are ATD cases or suspected cases. The employer shall give consideration to implementing barriers and air handling systems, where feasible. Employers shall document the results and the basis for the results of their consideration process. These control measures shall be included in the annual review of the Plan, in accordance with subsection (d)(3).

(2) The employer shall develop and implement effective written decontamination procedures, including appropriate engineering controls, for the cleaning and decontamination of work areas, vehicles, personal protective equipment, and other equipment.

(3) The employer shall provide information about infectious disease hazards to any contractor who provides temporary or contract employees who may ~~incur~~ be reasonably

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anticipated to have occupational exposures so that the contractors can institute precautions to protect their employees.

- (4) Engineering controls shall be used in workplaces that admit, house, or provide medical services to AirID cases or suspected cases, except in settings where home health care or home-based hospice care is being provided.
- (5) AirID cases or suspected cases shall be identified, and except in field operations and in settings where home health care or home-based hospice care is being provided, these individuals shall be:
 - (A) Provided with disposable tissues and hand hygiene materials and masked or placed in such a manner that contact with employees who are not wearing respiratory protection is eliminated or minimized until transfer or placement in an AII room or area can be accomplished and;
 - (B) Placed in an AII room or area or transferred to a facility with AII rooms or areas. The employer shall ensure that this placement or transfer is effected in a timely manner.
 - 1. Transfers within facility. Transfers to airborne infection isolation rooms or areas within the facility shall occur within 5 hours of identification. If there is no AII room or area available within this time, the employer shall transfer the individual to another suitable facility in accordance with subsection (e)(5)(B)2.
 - 2. Transfers to other facilities. Transfers to other facilities shall occur within 5 hours of identification, unless the employer documents, at the end of the 5-hour period, and at least every 24 hours thereafter, that each of the following:
 - a. The employer has contacted the local health officer;
 - b. There is no AII room or area available within that jurisdiction;
 - c. Reasonable efforts have been made to contact establishments outside of that jurisdiction, as provided in the Plan;
 - d. All applicable measures recommended by the local health officer or the Infection Control PLHCP have been implemented, ~~and,~~
 - e. All ~~susceptible~~ employees who enter the room or area housing the individual are provided with, and use, appropriate personal protective equipment and respiratory protection in accordance with subsection (g) and Section 5144, Respiratory Protection of these orders.

EXCEPTIONS to subsection (e)(5)(B)~~2~~:

- (1) Where the treating physician determines that transfer would be detrimental to a patient's condition, the patient need not be transferred. In that case the facility shall ensure that employees use respiratory protection when entering the room or area housing the individual. The patient's condition shall be reviewed at least every 24 hours to determine if transfer is safe, and the determination shall be recorded as described in the Plan in accordance with (d)(2)(~~HG~~). Once transfer is determined to be safe, transfer must be made within the time period set forth in subsection (e)(5)(B).

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(2) Where it is not feasible to provide AII rooms or areas to individuals suspected or confirmed to be infected with or carriers of novel or unknown ATPs, the employer shall provide other effective control measures to reduce the risk of transmission to employees, which shall include the use of respiratory protection in accordance with subsection (g) and Section 5144, Respiratory Protection of these orders.

(C) High-hazard procedures shall be conducted in AII rooms or areas, such as a ventilated booth or tent. Persons not performing the procedures shall be excluded from the area, unless they use the respiratory and personal protective equipment required for employees performing these procedures.

EXCEPTION to subsection (e)(5)(C): Where no AII room or area is available and the treating physician determines that it would be detrimental to the patient's condition to delay performing the procedure, high hazard procedures may be conducted in other areas. In that case, employees working in the room or area where the procedure is performed shall use respiratory protection, in accordance with subsection (g) and Section 5144, Respiratory Protection of these orders, and shall use all necessary personal protective equipment.

(D) Specific requirements for AII rooms and areas.

1. Hospital isolation rooms constructed in conformance with Title 24, California Code of Regulations, Section 417, et seq., and which are maintained to meet those requirements shall be considered to be in compliance with subsection (e)(5)(D)2.
2. Negative pressure shall be maintained in AII rooms or areas. The ventilation rate shall be 12 or more air changes per hour (ACH). The required ventilation rate may be achieved in part by using in-room high efficiency particulate air (HEPA) filtration or other air cleaning technologies, but in no case shall the outdoor air supply ventilation rate be less than six ACH. Hoods, booths, tents and other local exhaust control measures shall comply with Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings.
3. Negative pressure shall be visually demonstrated by smoke trails or equally effective means daily while a room or area is in use for AII.
4. Engineering controls shall be maintained, inspected and performance monitored for exhaust or recirculation filter loading and leakage at least annually, whenever filters are changed, and more often if necessary to maintain effectiveness. Where UVGI is used, it shall be used, maintained, inspected and controlled in accordance with Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings. Problems found shall be corrected in a reasonable period of time. If the problem(s) prevent the room from providing effective AII, then the room shall not be used for that purpose until the condition is corrected.

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5. Ventilation systems for AII rooms or areas shall be constructed, installed, inspected, operated, tested, and maintained in accordance with Section 5143, General Requirements of Mechanical Ventilation Systems, of these orders. Inspections, testing and maintenance shall be documented in writing, in accordance with subsection (j)(3)(~~EF~~).
6. Air from AII rooms or areas, and areas that are connected via plenums or other shared air spaces shall be exhausted directly outside, away from intake vents, employees, and the general public. Air that cannot be exhausted in such a manner or that must be recirculated must pass through HEPA filters before discharge or recirculation.
7. Ducts carrying air that may reasonably be anticipated to contain aerosolized *M. tuberculosis* or other AirIP shall be maintained under negative pressure for their entire length before in-duct HEPA filtration or until the ducts exit the building for discharge.
8. Doors and windows of AII rooms or areas shall be kept closed while in use for airborne infection isolation, except when doors are opened for entering or exiting and when windows are part of the ventilation system being used to achieve negative pressure.
9. When a case or suspected case vacates an AII room or area, the room or area shall be ventilated according to Table 1 in the Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings for a removal efficiency of 99.9 % before permitting employees to enter without respiratory protection.

(f) Laboratories.

- (1) This subsection applies to laboratory operations where employees perform procedures capable of aerosolizing ATPs-L.
NOTE: Employers with laboratory operations in which employees have direct contact with cases or suspected cases are also required to comply with applicable portions of subsections (d), (e), (g), (h), (i) and (j).
- (2) The biological safety officer shall perform a risk assessment in accordance with the methodology included in Section II of the BMBL for each agent and procedure involving the handling of ATPs-L. The biosafety officer shall record the safe practices required for each evaluated agent/procedure in the Biosafety Plan.
- (3) ~~(2)~~ The employer shall implement feasible engineering and work practice controls, in accordance with the risk assessment performed in subsection (f)(2), to minimize employee exposures to ATPs-L. Where exposure still remains after the institution of engineering and work practice controls, the employer shall provide, and ensure that employees use, personal protective equipment and, where necessary to control exposure, respiratory protection. Control measures shall be consistent with the recommendations in BMBL.

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- (4) ~~(3)~~ Biosafety Plan (BSP). The employer shall establish, implement, and maintain an effective written Biosafety Plan to minimize employee exposures to ATPs-L that may be transmitted by laboratory aerosols. The BSP may be incorporated into an existing Exposure Control Plan for bloodborne pathogens or an ATD Exposure Control Plan as described in subsection (d), and shall do all of the following:
- (A) Identify a biological safety officer(s) with the necessary knowledge, authority and responsibility for implementing the BSP.
 - (B) Include a list of all job classifications in which all or some employees have occupational exposure, and a list of all tasks and procedures in which employees have occupational exposure.
 - (C) Include a list of ATPs-L known or reasonably expected to be present in laboratory materials and the applicable biosafety measures.
 - (D) Include a requirement that all incoming materials containing ATPs-L are to be treated as containing the virulent or wild-type pathogen, until procedures have been conducted at the laboratory to verify that a pathogen has been deactivated or attenuated.
 - (E) Identify and describe the use of engineering controls, including containment equipment and procedures, to be used to minimize exposure to infectious or potentially infectious laboratory aerosols.
 - (F) Establish safe handling procedures and prohibit practices, such as sniffing *in vitro* cultures, that may increase employee exposure to infectious agents.
 - (G) Establish effective decontamination and disinfection procedures for laboratory surfaces and equipment.
 - (H) Identify and describe the use of the appropriate personal protective equipment to be used to minimize exposure to infectious or potentially infectious laboratory aerosols.
 - (I) Identify any operations or conditions in which respiratory protection will be required. The use of respiratory protection shall be in accordance with subsection (g) and Section 5144 of these orders.
 - (J) Establish emergency procedures for uncontrolled releases within the laboratory facility and untreated releases outside the laboratory facility. These procedures shall include effective means of reporting such incidents to the local health officer.
 - (K) Include a medical ~~surveillance services~~ program consistent with subsection (h), including the provision of all vaccinations as recommended by ~~the CDC or~~ CDPH applicable public health guidelines for the specific laboratory operations, and the methods for providing investigation and medical follow up for exposure incidents (laboratory).

EXCEPTION to subsection (f)~~(34)~~(K): Research and production laboratories in which it is not reasonable to expect that materials containing *M. Tuberculosis* will be present need not provide surveillance for LTBI.

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- (L) Include procedures for communication of hazards and employee training that complies with subsection (i). This shall include training in the employer's Biosafety Plan and emergency procedures.
- (M) Include an effective procedure for obtaining the active involvement of employees in reviewing and updating the Biosafety Plan with respect to the procedures performed by employees in their respective work areas or departments on an annual (or more frequent) basis.
- (N) Include procedures for the biological safety officer(s) to review plans for facility design and construction that will affect the control measures for ATPs-L.
- (O) Include procedures for inspection of laboratory facilities, including an audit of biosafety procedures. These inspections shall be performed at least annually. Hazards found during the inspection, and actions taken to correct hazards shall be recorded.

(5) ~~(4)~~ Recordkeeping shall be in accordance with subsection (j).

(g) Respiratory Protection.

- (1) Respirators provided for compliance with this section shall be approved by NIOSH for the purpose for which they are used.
- (2) Each employer who has any employee whose occupational exposure is based on entering any of the work settings or performing any of the tasks described in subsection (g)(4) shall establish, implement and maintain an effective written respiratory protection program that meets the requirements of Section 5144 of these orders, except as provided in subsections (g)(5) and (g)(6).

NOTE to subsection (g)(2): The respiratory protection program may be incorporated into the ATD Exposure Control Plan or the Biosafety Plan.

(3) Respirator selection.

(A) Where respirator use is required for protection against potentially infectious aerosols and is not required to meet the requirements of subsections (g)(3)(B) or (g)(3)(C), the employer shall provide a respirator that is at least as effective as an N95 filtering facepiece respirator, ~~unless the CDC or CDPH specifies the employer's evaluation of respiratory hazards determines that a more protective level respirator is necessary,~~ in which case the more protective respirator shall be provided.

(B) The employer shall provide a powered air purifying respirator (PAPR) with a High Efficiency Particulate Air (HEPA) filter(s), or a respirator providing equivalent or greater protection, to employees who perform high hazard procedures on AirID cases or suspected cases and to employees who perform high hazard procedures on cadavers potentially infected with ATPs, unless the employer determines that this use would interfere with the successful performance of the required task or tasks. This determination shall be documented in accordance with the ATD Plan and shall be reviewed by the employer and employees at least annually in accordance with subsection (d)(3).

EXCEPTION 1 to subsection (g)(3)(B): Where a high hazard procedure is performed by placing the patient in a booth, hood or other ventilated enclosure that effectively

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- contains and removes the aerosols resulting from the procedure, and the employee remains outside of the enclosure, the employee may use a respirator meeting the requirements of subsection (g)(3)(A).
- EXCEPTION 2 to subsection (g)(3)(B): Paramedics and other emergency medical personnel in field operations may use a P100 respirator in lieu of a PAPR.
- (C) Respirators used in laboratory operations to protect against infectious aerosols shall be selected in accordance with the risk assessment and biosafety plan, in accordance with subsection (f).
- (D) ~~(C)~~ Where respirators are necessary to protect the user from other hazards, including the uncontrolled release of microbiological spores, or exposure to chemical or radiologic agents, respirator selection shall also be made in accordance with Sections 5144, Respiratory Protection, and 5192, Hazardous Waste and Emergency Response Operations, of these orders, as applicable.
- (4) The employer shall provide, and ensure that employees use, a respirator selected in accordance with subsection (g)(3) and Section 5144 when the employee:
- (A) Enters an AII room or area in use for AII;
 - (B) Is present during the performance of procedures or services for an AirID case or suspected case;
 - (C) Repairs, replaces, or maintains air systems or equipment that may contain or generate aerosolized pathogens;
 - (D) Is working in an area occupied by an AirID case or suspected case, ~~and during decontamination procedures after the person has left the area~~ and as required by subsection (e)(5)(D)9;
 - (E) Is working in a residence where an AirID case or suspected case is known to be present;
 - (F) Is present during the performance of aerosol generating procedures on cadavers that are suspected of, or confirmed as, being infected with ~~airborne infectious aerosol~~ transmissible pathogens;
 - (G) Is performing a task for which the Biosafety Plan or Exposure Control Plan requires the use of respirators; or
 - (H) Transports an AirID case or suspected case within the facility or in an enclosed vehicle (e.g., van, car, ambulance or helicopter) ~~or who transports an AirID case or suspected case within the facility when that individual~~ the patient is not masked.
- EXCEPTIONS to subsection (g)(4)(H):
- (1) The employer shall not require or permit respirator use when an employee is operating a helicopter or other vehicle and the respirator may interfere with the safe operation of that vehicle. When employees do not use respirators, the employer shall provide other means of protection such as barriers or source control measures, where feasible.

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- (2) Law enforcement or corrections personnel who transport an airborne infectious disease case or suspected case in a vehicle need not use respiratory protection if all of the following conditions are met:
- i. A solid partition separates the passenger area from the area where employees are located;
 - ii. ~~The employer's~~ employer implements written procedures that specify the conditions of operation, including the condition of windows and fans;
 - iii. The employer tests (for example by the use of smoke tubes) the airflow in a representative vehicle (of the same model, year of manufacture, and partition design) under the specified conditions of operation, and finds that there is no detectable airflow from the passenger compartment to the employee area;
 - iv. The employer records and maintains the results, in accordance with subsection (j)(3)(~~FE~~); and
 - v. The person performing the test is knowledgeable about the assessment of air handling systems.
- (5) Medical evaluation: The employer shall provide a medical evaluation, in accordance with Section 5144(e) of these orders, to determine the employee's ability to use a respirator before the employee is fit tested or required to use the respirator. For employees who use respirators solely for compliance with subsections (g)(3)(A) and (g)(3)(B), the alternate questionnaire in Appendix B may be used.
- (6) Fit testing.
- (A) The employer shall perform either quantitative or qualitative fit tests in accordance with the procedures outlined in Appendix A of Section 5144, Respiratory Protection, of these orders. The fit test shall be performed on the same size, make, model and style of respirator as the employee will use. When quantitative fit testing is performed, the employer shall not permit an employee to wear a filtering facepiece respirator or other half-facepiece respirator, unless a minimum fit factor of one hundred (100) is obtained. When fit testing single use respirators, a new respirator shall be used for each employee.
- (B) The employer shall ensure that each employee who is assigned to use a filtering facepiece or other tight-fitting respirator passes a fit test:
1. At the time of initial fitting;
 2. When a different size, make, model or style of respirator is used; and
 3. At least annually thereafter.

EXCEPTION to subsection (g)(6)(B)3: Until January 1, 2014, employers may increase the interval for repeat fit testing to no more than two years for employees who do not perform high hazard procedures and are not using respirators for protection against laboratory generated aerosols. Employers shall provide to each employee who is not fit-tested within the previous 12 months a respirator fit-test screening that includes the information in Appendix G, and that obtains a response to the questions included

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- in Appendix G. As of January 1, 2015, an employee who uses a respirator under this section shall have been fit-tested within the previous 12 months.
- (C) The employer shall conduct an additional fit test when the employee reports, or the employer, PLHCP, supervisor, or program administrator makes visual observations of changes in the employee's physical condition that could affect respirator fit. Such conditions include, but are not limited to, facial scarring, dental changes, cosmetic surgery, or an obvious change in body weight.
- (D) If, after passing a fit test, the employee subsequently notifies the employer, program administrator, supervisor, or PLHCP that the fit of the respirator is unacceptable, the employee shall be given a reasonable opportunity to select a different respirator facepiece and to be retested.
- (7) The employer shall ensure that each respirator user is provided with initial and annual training in accordance with Section 5144, Respiratory Protection of these orders.
- (h) Medical Surveillance Services.**
- (1) Each employer who has any employee with occupational exposure shall provide the employee with medical ~~surveillance services~~ for tuberculosis and other ATDs, and infection with ATPs and ATPs-L, in accordance with applicable public health guidelines, as recommended by the CDC and/or the CDPH for the type of work setting and disease. When an employer is also acting as the evaluating health care professional, the employer shall advise the employee following an exposure incident that the employee may refuse to consent to vaccination, post-exposure evaluation and follow-up from the employer-health care professional. When consent is refused, the employer immediately shall make available a confidential vaccination, medical evaluation or follow-up from a PLHCP other than the exposed employee's employer.
- (2) Medical ~~surveillance services provisions~~, including vaccinations, tests, examinations, evaluations, determinations, procedures, and medical management and follow-up, shall be:
- (A) Performed by or under the supervision of a PLHCP;
- (B) Provided according to applicable public health guidelines ~~any CDC and CDPH recommendations that are current at the time these evaluations and procedures take place~~; and
- (C) Provided in a manner that ensures the confidentiality of employees and patients. Test results and other information regarding exposure incidents and TB conversions shall be provided without providing the name of the source individual.
- (3) The employer shall make ~~surveillance assessment~~ for latent tuberculosis infection (LTBI) available to all employees with occupational exposure. Surveillance Assessment procedures shall be in accordance with ~~the most recent recommendations of the CDC and CDPH~~ applicable public health guidelines.
- (A) TB tests and other forms of TB surveillance assessment shall be provided at least annually, and more frequently, if ~~the CDC, CDPH~~ applicable public health

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guidelines or the local health officer recommends more frequent testing. Employees with baseline positive TB test shall have an annual symptom screen.

- (B) The employer shall refer employees who experience a TB conversion to a PLHCP knowledgeable about TB for evaluation.
1. The employer shall provide the PLHCP with a copy of this standard and the employee's TB test records. If the employer has determined the source of the infection, the employer shall also provide any available diagnostic test results including drug susceptibility patterns relating to the source patient.
 2. The employer shall request that the PLHCP, with the employee's consent, perform any necessary diagnostic tests and inform the employee about appropriate treatment options.
 3. The employer shall request that the PLHCP determine if the employee is a TB case or suspected case, and to do all of the following, if the employee is a case or suspected case:
 - a. Inform the employee and the local health officer in accordance with Title 17.
 - b. Consult with the local health officer and inform the employer of any infection control recommendations related to the employee's activity in the workplace.
 - c. Make a recommendation to the employer regarding precautionary removal due to suspect active disease, in accordance with subsection (h)(8), and provide the employer with a written opinion in accordance with subsection (h)(9).
- (C) TB conversions shall be recorded in accordance with California Code of Regulations, Title 8, Section 14300 et seq.
- (D) Unless it is determined that the TB test conversion is not occupational, the employer shall investigate the circumstances of the conversion, and correct any deficiencies found during the investigation. The investigation shall be documented in accordance with subsection (j).

EXCEPTION to subsection (h)(3): Research and production laboratories in which *M. tuberculosis* containing materials are not reasonably anticipated to be present, need not provide ~~surveillance~~ assessment for LTBI infection.

(4) Laboratory tests shall be conducted by an accredited laboratory.

(5) The employer shall make available to all susceptible health care workers with occupational exposure all vaccine doses listed in Appendix E. Employees in laboratory operations outside of health care settings, and within the scope of subsection (f), shall be provided with vaccines in accordance with the BMBL ~~CDC and CDPH recommendations~~ for the specific laboratory operations.

(A) Recommended vaccinations shall be made available to all employees who have occupational exposure after the employee has received the training required in subsection (c) or (i) and within 10 working days of initial assignment unless:

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1. The employee has previously received the recommended vaccination(s) and is not due to receive another vaccination dose; or
2. A PLHCP has determined that the employee is immune in accordance with applicable public health ~~current CDC and CDPH~~ guidelines; or
3. The vaccine(s) is contraindicated for medical reasons.

(B) The employer shall make additional vaccine doses ~~ation(s)~~ available to employees within 120 days of the issuance of new applicable public health guidelines ~~recommending the additional dose CDC or CDPH recommendations~~.

(C) The employer shall not make participation in a prescreening serology program a prerequisite for receiving a vaccine, unless ~~CDC or CDPH~~ applicable public health guidelines recommend this prescreening prior to administration of the vaccine.

(D) If the employee initially declines a vaccination but at a later date, while still covered under the standard, decides to accept the vaccination, the employer shall make the vaccination available in accordance with subsection (h)(5)(A) within 10 working days of receiving a written request from the employee. ~~that request, in accordance with subsection (h)(5)(A).~~

(E) The employer shall ensure that employees who decline to accept a recommended and offered vaccination sign the statement in Appendix C1 for each declined vaccine.

(F) The employer shall request the PLHCP administering a vaccination or determining immunity to provide only the following information to the employer:

1. The employee's name and employee identifier.
2. The date of the vaccine dose or determination of immunity.
3. Whether the employee is immune to the disease, and whether there are any specific restrictions on the employee's exposure or ability to receive vaccine.
4. Whether an additional vaccination dose is required, and if so, the date the additional vaccination dose should be provided.

EXCEPTION to subsection (h)(5): Where the employer cannot implement these procedures because of the lack of availability of vaccine, the employer shall document efforts made to obtain the vaccine in a timely manner and inform employees of the status of the vaccine availability, including when the vaccine is likely to become available. The employer shall check on the availability of the vaccine at least every ~~10 working days~~ 60 calendar days and inform employees when the vaccine becomes available.

(6) Exposure Incidents.

(A) ~~A health care provider, or the employer of a health care provider~~ An employer who determines that a person is an RATD case or suspected case shall ~~1. Report,~~ or ensure that the health care provider reports, the case to the local health officer, in accordance with Title 17.

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(B) ~~2. Determine~~ In addition to the report required in subsection (h)(6)(A), the employer in the facility, service or operation that originates the report shall determine, to the extent that the information is available in the employer's records, whether the employee(s) of any other employer(s) may have had contact with the case or suspected case while performing activities within the scope of this section. The employer shall notify the other employer(s) within a timeframe that will both provide reasonable assurance that there will be adequate time for the employee to receive effective medical intervention to prevent disease or mitigate the disease course, and will also permit the prompt initiation of an investigation to identify exposed employees. In no case, shall the notification be longer than 72 hours after the report to the local health officer. The notification shall include ~~24 hours of diagnosis of~~ the date, time, and nature of the potential exposure, and provide any other information that is necessary for the other employer(s) to evaluate the potential exposure of his or her employees. The notifying employer shall not provide the identity of the source patient to the other employers.

NOTE 1 to subsection (h)(6)(A): These employees may include, but are not limited to, paramedics, emergency medical technicians, emergency responders, home health care personnel, homeless shelter personnel, personnel at referring health care facilities or agencies, and corrections personnel.

NOTE 2 to subsection (h)(6)(B): Some diseases, such as meningococcal disease, require prompt prophylaxis of exposed individuals to prevent disease. Some diseases, such as varicella, have a limited window in which to administer vaccine to non-immune contacts. Exposure to some diseases may create a need to temporarily remove an employee from certain duties during a potential period of communicability. For other diseases such as tuberculosis there may not be a need for immediate medical intervention, however prompt follow up is important to the success of identifying exposed employees.

(C) ~~(B)~~ Each employer who becomes aware that his or her employees may have been exposed to an RATD case or suspected case, or to an exposure incident involving an ATP-L shall do all of the following:

1. Within a timeframe that is reasonable for the specific disease, as described in subsection (h)(6)(B), but in no case later than 72 hours following, as applicable, the employer's report to the local health officer or the receipt of notification from another employer or the local health officer, ~~24 hours of becoming aware of the potential exposure,~~ conduct an analysis of the exposure scenario to determine which employees had significant exposures. This analysis shall be conducted by an individual knowledgeable in the mechanisms of exposure to ATPs or ATPs-L, and shall record the names and any other employee identifier used in the workplace ~~identification numbers of~~

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persons who were included in the analysis. The analysis shall also record the basis for any determination that an employee need not be included in post-exposure follow-up because the employee did not have a significant exposure or because a PLHCP determined that the employee is immune to the infection in accordance with ~~current applicable public health guidelines CDC or CDPH guidelines~~. The exposure analysis shall be made available to the local health officer upon request. The name of the person making the determination, and the identity of any PLHCP or local health officer consulted in making the determination shall be recorded.

2. Within a timeframe that is reasonable for the specific disease, as described in subsection (h)(6)(B), but in no case later than 48-96 hours of becoming aware of the potential exposure, notify employees who had significant exposures of the date, time, and nature of the exposure.
 3. As soon as feasible, provide post-exposure medical evaluation to all employees who had a significant exposure. The evaluation shall be conducted by a PLHCP knowledgeable about the specific disease, including appropriate vaccination, prophylaxis and treatment. For *M. tuberculosis*, and for other pathogens where recommended by ~~the CDC or CDPH~~ applicable public health guidelines, this shall include testing of the isolate from the source individual or material for drug susceptibility, unless the PLHCP determines that it is not feasible.
 4. Obtain from the PLHCP a recommendation regarding precautionary removal in accordance with subsection (h)(8), and a written opinion in accordance with subsection (h)(9).
 5. Determine, to the extent that the information is available in the employer's records, whether employees of any other employers may have been exposed to the case or material. The employer shall notify these other employers within a time frame that is reasonable for the specific disease, as described in subsection (h)(6)(B), but in no case later than 72-24 hours of becoming aware of the exposure incident of the nature, date, and time of the exposure, and shall provide the contact information for the diagnosing PLHCP. The notifying employer shall not provide the identity of the source patient to other employers.
- (7) Information provided to the Physician or Other Licensed Health Care Professional.
- (A) Each employer shall ensure that all PLHCPs responsible for making determinations and performing procedures as part of the medical ~~surveillance services~~ program are provided a copy of this standard and applicable ~~CDC and CDPH~~ public health guidelines. For respirator medical evaluations, the employer shall provide information regarding the type of respiratory protection used, a description of the work effort required, any special environmental conditions that exist (e.g., heat,

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- confined space entry), additional requirements for protective clothing and equipment, and the duration and frequency of respirator use.
- (B) Each employer shall ensure that the PLHCP who evaluates an employee after an exposure incident is provided the following information:
1. A description of the exposed employee's duties as they relate to the exposure incident;
 2. The circumstances under which the exposure incident occurred;
 3. Any available diagnostic test results, including drug susceptibility pattern or other information relating to the source of exposure that could assist in the medical management of the employee; and
 4. All of the employer's medical records for the employee that are relevant to the management of the employee, including tuberculin skin test results and other relevant tests for ATP infections, vaccination status, and determinations of immunity.
- (8) Precautionary removal recommendation from the physician or other licensed health care professional.
- (A) Each employer who provides a post-exposure evaluation in accordance with this Section, or an evaluation of an employee's TB conversion in accordance with subsection (h)(3) shall request from the PLHCP an opinion regarding whether precautionary removal from the employee's regular assignment is necessary to prevent spread of the disease agent by the employee and what type of alternate work assignment may be provided. The employer shall request that the PLHCP convey to the employer any recommendation for precautionary removal immediately via phone or fax and that the PLHCP document the recommendation in the written opinion as required in subsection (h)(9).
- (B) Where the PLHCP recommends precautionary removal, or where the local health officer recommends precautionary removal, the employer shall maintain until the employee is determined to be noninfectious, the employee's earnings, seniority, and all other employee rights and benefits, including the employee's right to his or her former job status, as if the employee had not been removed from his or her job or otherwise medically limited.
- EXCEPTION to subsection (h)(8)(B): Precautionary removal provisions do not extend to any period of time during which the employee is unable to work for reasons other than precautionary removal.
- (9) Written opinion from the physician or other licensed health care professional.
- (A) Each employer shall obtain, and provide the employee with a copy of, the written opinion of the PLHCP within 15 working days of the completion of all medical evaluations required by this section.
- (B) For respirator use, the physician's opinion shall have the content required by Section 5144(e)(6) of these orders.

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(C) For TB conversions and all RATD and ATP-L exposure incidents, the written opinion shall be limited to the following information:

1. The employee's TB test status or applicable RATD test status for the exposure of concern;
2. The employee's infectivity status;
3. A statement that the employee has been informed of the results of the medical evaluation and has been offered any applicable vaccinations, prophylaxis, or treatment;
4. A statement that the employee has been told about any medical conditions resulting from exposure to TB, other RATD, or ATP-L that require further evaluation or treatment and that the employee has been informed of treatment options; and
5. Any recommendations for precautionary removal from the employee's regular assignment.

(D) All other findings or diagnoses shall remain confidential and shall not be included in the written report.

- (10) The employer shall make available seasonal influenza vaccine to all employees with occupational exposure. The employer shall ensure that each employee who declines to accept the seasonal influenza vaccine signs the statement in Appendix C2.

EXCEPTION 1 to subsection (h)(10): Seasonal influenza vaccine shall be provided during the period designated by the CDC for administration, and need not be provided outside of those periods.

EXCEPTION 2 to subsection (h)(10): In lieu of the statement in Appendix C2, the employer may utilize an influenza vaccine declination statement acceptable to the CDPH in accordance with Health and Safety Code Section 1288.7.

(i) Training.

- (1) Employers shall ensure that all employees with occupational exposure participate in a training program.

- (2) Employers shall provide training as follows:

(A) At the time of initial assignment to tasks where occupational exposure may take place;

(B) At least annually thereafter, not to exceed 12 months from the previous training;

(C) For employees who have received training on aerosol transmissible diseases in the year preceding the effective date of the standard, only training with respect to the provisions of the standard that were not included previously need to be provided.

(D) When changes, such as introduction of new engineering or work practice controls, modification of tasks or procedures or institution of new tasks or procedures, affect the employee's occupational exposure or control measures. The additional training may be limited to addressing the new exposures or control measures.

- (3) Training material appropriate in content and vocabulary to the educational level, literacy, and language of employees shall be used.

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- (4) ~~(3)~~ The training program shall contain at a minimum the following elements:
- (A) An accessible copy of the regulatory text of this standard and an explanation of its contents.
 - (B) A general explanation of ATDs including the signs and symptoms of ATDs that require further medical evaluation.
 - (C) An explanation of the modes of transmission of ATPs or ATPs-L and applicable source control procedures.
 - (D) An explanation of the employer's ATD Exposure Control Plan and/or Biosafety Plan, and the means by which the employee can obtain a copy of the written plan and how they can provide input as to its effectiveness.
 - (E) An explanation of the appropriate methods for recognizing tasks and other activities that may expose the employee to ATPs or ATPs-L.
 - (F) An explanation of the use and limitations of methods that will prevent or reduce exposure to ATPs or ATPs-L including appropriate engineering and work practice controls, decontamination and disinfection procedures, and personal and respiratory protective equipment.
 - (G) An explanation of the basis for selection of personal protective equipment, its uses and limitations, and the types, proper use, location, removal, handling, cleaning, decontamination and disposal of the items of personal protective equipment employees will use.
 - (H) A description of the employer's TB surveillance procedures, including the information that persons who are immune-compromised may have a false negative test for LTBI.
EXCEPTION: Research and production laboratories do not need to include training on surveillance for LTBI if *M. tuberculosis* containing materials are not reasonably anticipated to be present in the laboratory.
 - (I) Training meeting the requirements of Section 5144(k) of these orders for employees whose assignment includes the use of a respirator.
 - (J) Information on the vaccines made available by the employer, including information on their efficacy, safety, method of administration, the benefits of being vaccinated, and that the vaccine and vaccination will be offered free of charge.
 - (K) An explanation of the procedure to follow if an exposure incident occurs, including the method of reporting the incident, the medical follow-up that will be made available, and post-exposure evaluation.
 - (L) Information on the employer's surge plan as it pertains to the duties that employees will perform. As applicable, this training shall cover the plan for surge receiving and treatment of patients, patient isolation procedures, surge procedures for handling of specimens, including specimens from persons who may have been contaminated as the result of a release of a biological agent, how to access supplies needed for the response including personal protective equipment and respirators, decontamination

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facilities and procedures, and how to coordinate with emergency response personnel from other agencies.

~~(M) An opportunity for interactive questions and answers with the person conducting the training session.~~

(5) Every training program shall include an opportunity for interactive questions and answers with a person who is knowledgeable in the subject matter of the training as it relates to the workplace that the training addresses and who is also knowledgeable in the employer's ATD exposure control or biosafety plan. Training not given in person shall fulfill all the subject matter requirements of subsections (i)(4) and shall provide for interactive questions to be answered within 24 hours by a knowledgeable person as described above.

~~(4) The person conducting the training shall be knowledgeable in the subject matter covered by the training program as it relates to the workplace that the training will address.~~

~~(5) Training material appropriate in content and vocabulary to the educational level, literacy, and language of employees shall be used.~~

(j) Recordkeeping.

(1) Medical records.

(A) The employer shall establish and maintain an accurate medical record for each employee with occupational exposure, in accordance with Section 3204, Access to Employee Exposure and Medical Records, of these orders.

NOTE to subsection (j)(1)(A): This record may be combined with the medical record required by Section 5193, Bloodborne Pathogens, of these orders, but may not be combined with non-medical personnel records.

(B) This record shall include:

1. The employee's name and any other employee identification used in the workplace~~number~~;
2. The employee's vaccination status for all vaccines required by this standard, including the information provided by the PLHCP in accordance with subsection (h)(5)(F), any vaccine record provided by the employee, dates of all vaccinations,~~any medical records relevant to the employee's ability to receive vaccination as required by subsection (h)(5), any determinations of immunity, and any signed declination forms;~~

Exception to subsection (j)(1)(B)2.: As to seasonal influenza vaccine, the medical record need only contain a declination form for the most recent seasonal influenza vaccine.

3. A copy of all written opinions provided by a PLHCP in accordance with this standard, and the results of all TB assessments; all results of examinations, medical testing, and follow up procedures as required by this section; and
4. ~~The employer's copy of the PLHCP's written opinion as required by subsection (h)(9); and~~

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- ~~4. 5.~~ A copy of the information regarding an exposure incident that was provided to the PLHCP as required by subsection (h)(7)(B).
- (C) Confidentiality. The employer shall ensure that all employee medical records required by this section are:
1. Kept confidential; and
 2. Not disclosed or reported without the employee's express written consent to any person within or outside the workplace except as permitted by this section or as may be required by law.
- ~~NOTE~~ NOTE to subsection (j)(1)(C) : These provisions do not apply to records that do not contain individually identifiable medical information, or from which individually identifiable medical information has been removed.
- (D) The employer shall maintain the medical records required by this section for at least the duration of employment plus 30 years in accordance with Section 3204, Access to Employee Exposure and Medical Records, of these orders.
- (2) Training records.
- (A) Training records shall include the following information:
1. The date(s) of the training session(s);
 2. The contents or a summary of the training session(s);
 3. The names and qualifications of persons conducting the training or who are designated to respond to interactive questions; and
 4. The names and job titles of all persons attending the training sessions.
- (B) Training records shall be maintained for 3 years from the date on which the training occurred.
- (3) Records of implementation of ATD Plan and/or Biosafety Plan.
- (A) Records of annual review of the ATD Plan and Biosafety Plan shall include the name(s) of the person conducting the review, the dates the review was conducted and completed, the name(s) and work area(s) of employees involved, and a summary of the conclusions. The record shall be retained for three years.
- (B) Records of exposure incidents shall be retained and made available as employee exposure records in accordance with Section 3204. These records shall include:
1. The date of the exposure incident;
 2. The names, and any other employee identifiers used in the workplace, of employees who were included in the exposure evaluation;
 3. The disease or pathogen to which employees may have been exposed;
 4. The name and job title of the person performing the evaluation;
 5. The identify of any local health officer and/or PLHCP consulted;
 6. The date of the evaluation; and
 7. The date of contact and contact information for any other employer who either notified the employer or was notified by the employer regarding potential employee exposure.

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- (C) ~~(B)~~ Records of the unavailability of vaccine shall include the name of the person who determined that the vaccine was not available, the name and affiliation of the person providing the vaccine availability information, and the date of the contact. This record shall be retained for three years.
- (D) ~~(C)~~ Records of the unavailability of AII rooms or areas shall include the name of the person who determined that an AII room or area was not available, the names and the affiliation of persons contacted for transfer possibilities, and the date of the contact, the name and contact information for the local health officer providing assistance, and the times and dates of these contacts. This record, which shall not contain a patient's individually identifiable medical information, shall be retained for three years.
- (E) ~~(D)~~ Records of decisions not to transfer a patient to another facility for AII for medical reasons shall be documented in the patient's chart, and a summary shall be provided to the Plan administrator providing only the name of the physician determining that the patient was not able to be transferred, the date and time of the initial decision and the date, time and identity of the person(s) who performed each daily review. The summary record, which shall not contain a patient's individually identifiable medical information, shall be retained for three years.
- (F) ~~(E)~~ Records of inspection, testing and maintenance of non-disposable engineering controls including ventilation and other air handling systems, air filtration systems, containment equipment, biological safety cabinets, and waste treatment systems shall be maintained for a minimum of five years and shall include the name(s) and affiliation(s) of the person(s) performing the test, inspection or maintenance, the date, and any significant findings and actions that were taken.
- (G) ~~(F)~~ Records of the respiratory protection program shall be established and maintained in accordance with Section 5144, Respiratory Protection, of these orders. Employers who provide fit-test screening, in accordance with the exception to subsection (g)(6)(B)3 shall retain the screening record for two years.
- (4) Availability.
- (A) The employer shall ensure that all records, other than the employee medical records more specifically dealt with in subsection (j)(4)(C), required to be maintained by this section shall be made available upon request to the Chief and NIOSH and the local health officer for examination and copying.
- (B) Employee training records, the exposure control plan and/or biosafety plan, and records of implementation of the ATD exposure control plan and biosafety plan, other than medical records containing individually identifiable medical information required by this subsection shall be made available as employee exposure records, in accordance with Section 3204(e)(1) provided upon request to employees, and employee representatives, the Chief and NIOSH for examination and copying.
- (C) Employee medical records required by this subsection shall be provided upon request to the subject employee, anyone having the written consent of the subject employee, the local health officer, and to the Chief and NIOSH in accordance with Section 3204.

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of these orders, Access to Employee Exposure and Medical Records, ~~of these orders~~
for examination and copying.

(5) Transfer of Records.

(A) The employer shall comply with the requirements involving the transfer of employee medical and exposure records that are set forth in Section 3204, Access to Employee Exposure and Medical Records, of these orders.

(B) If the employer ceases to do business and there is no successor employer to receive and retain the records for the prescribed period, the employer shall notify DOSH and NIOSH, at least three months prior to the disposal of the records and shall transmit them to NIOSH, if required by NIOSH to do so, within that three-month period.

NOTE: Authority cited: Section 142.3, Section 6308; Labor Code. Reference: Section 142.3, Labor Code, Section 6308, 8 CCR 332.3.

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Appendix A – Aerosol Transmissible Diseases/Pathogens (Mandatory)

This appendix contains a list of diseases and pathogens which are to be considered aerosol transmissible pathogens or diseases for the purpose of Section 5199. Employers are required to provide the protections required by Section 5199 according to whether the disease or pathogen requires airborne infection isolation or droplet precautions as indicated by the two lists below. ~~regarding airborne infectious diseases or pathogens for those pathogens and diseases listed below under “Airborne Infectious Diseases/Pathogens.”~~

Airborne Infectious Diseases/Pathogens Requiring Airborne Infection Isolation⁺

Aerosolizable spore-containing powder or other substance that is capable of causing serious human disease,
e.g. Anthrax/*Bacillus anthracis*
Avian influenza/Avian influenza A viruses (strains capable of causing serious disease in humans)
Varicella disease (chickenpox, shingles)/Varicella zoster and Herpes zoster viruses, disseminated disease in any patient. Localized disease in immunocompromised patient until disseminated infection ruled out
Measles (rubeola)/Measles virus
Monkeypox/Monkeypox virus
Novel or unknown pathogens
Severe acute respiratory syndrome (SARS)/~~SARS associated coronavirus (SARS-CoV)~~
Smallpox (variola)/Variola virus (~~see vaccinia for management of vaccinated persons~~)
Tuberculosis (TB)/*Mycobacterium tuberculosis* -- Extrapulmonary, draining lesion; Pulmonary or laryngeal disease, confirmed; Pulmonary or laryngeal disease, suspected
Any other disease for which ~~the CDC or CDPH~~ public health guidelines recommends airborne infection isolation

Diseases/Pathogens Requiring Droplet Precautions

Diphtheria/~~*Corynebacterium diphtheriae*~~ -- pharyngeal
Epiglottitis, due to *Haemophilus influenzae* type b
~~Group A Streptococcal (GAS) disease (strep throat, necrotizing fasciitis, impetigo)/Group A streptococcus~~
Haemophilus influenzae Serotype b (Hib) disease/*Haemophilus influenzae* serotype b -- Infants and children
Influenza, human (typical seasonal variations)/influenza viruses
Meningitis
 Haemophilus influenzae, type b known or suspected
 Neisseria meningitidis (meningococcal) known or suspected
Meningococcal disease/~~*Neisseria meningitidis*~~ sepsis, pneumonia (see also meningitis)
Mumps (infectious parotitis)/Mumps virus
Mycoplasmal pneumonia/~~*Mycoplasma pneumoniae*~~
Parvovirus B19 infection (erythema infectiosum, fifth disease)/~~Parvovirus B19~~
Pertussis (whooping cough)/~~*Bordetella pertussis*~~
Pharyngitis in infants and young children/Adenovirus, Orthomyxoviridae, Epstein-Barr virus, Herpes simplex virus, Pneumonia
 Adenovirus
 Haemophilus influenzae Serotype b, infants and children
 Meningococcal
 ~~*Chlamydia pneumoniae*~~
 Mycoplasma, primary atypical pneumoniae
 ~~*Neisseria meningitidis*~~

⁺ ~~Airborne infection isolation includes implementation of droplet precautions~~

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~~*Streptococcus pneumoniae* Group A~~
Pneumonic plague/*Yersinia pestis*
Rubella virus infection (German measles) (~~also see congenital rubella~~)/Rubella virus
~~Scarlet fever in infants and young children/Group A streptococcus, Serious invasive disease~~
Severe acute respiratory syndrome (SARS)
Streptococcal disease (group A streptococcus)
Skin, wound or burn, Major
Pharyngitis in infants and young children
Pneumonia
Scarlet fever in infants and young children
Serious invasive disease

Viral hemorrhagic fevers due to Lassa, Ebola, Marburg, Crimean-Congo fever viruses, ~~and Hantaviruses~~ (airborne infection isolation and respirator use may be required for aerosol-generating procedures)
Any other disease for which ~~the CDC or CDPH~~ public health guidelines recommends droplet precautions

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Aerosol Transmissible Diseases

Appendix B – Alternate Respirator Medical Evaluation Questionnaire (This Appendix is Mandatory if the Employer chooses to use a Respirator Medical Evaluation Questionnaire other than the Questionnaire in Section 5144 Appendix C)

To the PLHCP employer: Answers to questions in Section 1, and to question 6 in Section 2 do not require a medical examination. Employees must be provided with a confidential means of contacting the health care professional who will review this questionnaire.

To the employee: Can you read and understand this questionnaire (circle one): Yes No

Your employer must allow you to answer this questionnaire during normal working hours, or at a time and place that is convenient to you. To maintain your confidentiality, your employer or supervisor must not look at or review your answers, and your employer must tell you how to deliver or send this questionnaire to the health care professional who will review it.

Section 1. The following information must be provided by every employee who has been selected to use any type of respirator (please print).

Today's date: _____

Name: _____ Job Title: _____

Your age (to nearest year): _____ Sex (circle one): Male Female

Height: _____ ft. _____ in. Weight: _____ lbs.

Phone number where you can be reached (include the Area Code): () _____

The best time to phone you at this number: _____

Has your employer told you how to contact the health care professional who will review this questionnaire (circle one) : Yes No

Check the type of respirator you will use (you can check more than one category):

N, R, or P disposable respirator (filter-mask, non-cartridge type only).

Other type (ex, half- or full-facepiece type, PAPR, supplied-air, SCBA). (fill in type here) _____

Have you worn a respirator (circle one): Yes No

If "yes," what type(s): _____

Section 2. Questions 1 through 6 below must be answered by every employee who has been selected to use any type of respirator (please circle "yes" or "no").

1. Have you ever had any of the following conditions?

Allergic reactions that interfere with

your breathing:	Yes	No	What did you react to? _____
Claustrophobia (fear of closed-in places)	Yes	No	

2. Do you currently have any of the following symptoms of pulmonary or lung illness?

Shortness of breath when walking fast on level ground or walking up a slight hill or incline:	Yes	No	Coughing that produces phlegm (thick sputum):	Yes	No
Have to stop for breath when walking at your own pace on level ground:	Yes	No	Coughing up blood in the last month:	Yes	No
Shortness of breath that interferes with your job:	Yes	No	Wheezing that interferes with your job:	No	Yes
			Chest pain when you breathe deeply:	Yes	No

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Any other symptoms that you think
may be related to lung problems:

Yes No

3. Do you currently have any of the following cardiovascular or heart symptoms?

Frequent pain or tightness in your chest:

Yes No

Pain or tightness in your chest that interferes
with your job:

Yes No

Pain or tightness in your chest during
physical activity:

Yes No

Any other symptoms that you think may be
related to heart or circulation problems:

Yes No

4. Do you currently take medication for any of the following problems?

Breathing or lung problems:

Yes No

Heart trouble:

Yes No

Nose, throat or sinuses

Yes No

Are your problems under control with these
medications?

Yes No

5. If you've used a respirator, have you ever had any of the following problems while respirator is being used?

(If you've never used a respirator, check the following space and go to question 6:) _____

Skin allergies or rashes:

Yes No

General weakness or fatigue:

Yes No

Anxiety:

Yes No

Any other problem that interferes with your use of a respirator:

Yes No

6. Would you like to talk to the health care professional who will review this questionnaire about your answers to this questionnaire:

Yes No

Employee Signature

Date

PLHCP Signature

Date

Appendix C1 – Vaccination Declination Statement (Mandatory)

The employer shall ensure that employees who decline to accept a recommended vaccination offered by the employer sign and date the following statement as required by subsection (h)(5)(E):

I understand that due to my occupational exposure to aerosol transmissible diseases, I may be at risk of acquiring infection with _____ (name of disease or pathogen). I have been given the opportunity to be vaccinated against this disease or pathogen at no charge to me. However, I decline this vaccination at this time. I understand that by declining this vaccine, I continue to be at risk of acquiring _____, a serious disease. If in the future I continue to have occupational exposure to aerosol transmissible diseases and want to be vaccinated, I can receive the vaccination at no charge to me.

Employee Signature

Date

Appendix C2 – Seasonal Influenza Vaccination Declination Statement (Mandatory)

The employer shall ensure that employees who decline to accept the seasonal influenza vaccination offered by the employer sign and date the following statement as required by subsection (h)(~~5~~10)(E):

I understand that due to my occupational exposure to aerosol transmissible diseases, I may be at risk of acquiring seasonal influenza. I have been given the opportunity to be vaccinated against this infection at no charge to me. However, I decline this vaccination at this time. I understand that by declining this vaccine, I continue to be at increased risk of acquiring influenza. If, during the season for which the CDC recommends administration of the influenza vaccine, I continue to have occupational exposure to aerosol transmissible diseases and want to be vaccinated, I can receive the vaccination at no charge to me.

Employee Signature

Date

Appendix D: Aerosol Transmissible Pathogens – Laboratory (Mandatory)

This appendix contains a list of agents that, when reasonably anticipated to be present, require a laboratory to comply with Section 5199 for laboratory operations, by performing a risk assessment and establishing a biosafety plan that includes appropriate control measures as identified in the standard. ~~It includes those pathogens for which CDC specifically recommends 1) aerosol control or 2) Biosafety Level 3 (BSL-3) or higher practices, personal protective equipment, containment devices, or facilities.~~

Adenovirus ~~(HICPAC)~~ (in clinical specimens and in cultures or other materials derived from clinical specimens)

Arboviruses, unless identified individually elsewhere in this list (large quantities or high concentrations* of arboviruses for which CDC recommends BSL-2, e.g., dengue virus; potentially infectious clinical materials, infected tissue cultures, animals, or arthropods involving arboviruses for which CDC recommends BSL-3 or higher, e.g., Japanese encephalitis, West Nile virus, Yellow Fever)

Arenaviruses (large quantities or high concentrations of arenaviruses for which CDC recommends BSL-2, e.g., Pichinde virus; potentially infectious clinical materials, infected tissue cultures, animals, or arthropods involving arenaviruses for which CDC recommends BSL-3 or higher, e.g., Flexal virus)

Bacillus anthracis (activities with high potential for aerosol production**, large quantities or high concentrations, screening environmental samples from *b. anthracis* - contaminated locations)

Blastomyces dermatitidis (sporulating mold-form cultures, processing environmental materials known or likely to contain infectious conidia)

Bordetella pertussis (aerosol generation, or large quantities or high concentrations)

Brucella abortus, *B. canis*, *B. "maris"*, *B. melitensis*, *B. suis* (cultures, experimental animal studies, products of conception containing or believed to contain pathogenic *Brucella* spp.)

Burkholderia mallei, *B. pseudomallei* (potential for aerosol or droplet exposure, handling infected animals, large quantities or high concentrations)

Cercopithecine herpesvirus (see Herpesvirus simiae)

Chlamydia pneumoniae (activities with high potential for droplet or aerosol production, large quantities or high concentrations)

Chlamydia psittaci (activities with high potential for droplet or aerosol production, large quantities or high concentrations, non-avian strains, infected caged birds, necropsy of infected birds and diagnostic examination of tissues or cultures known to contain or be potentially infected with *C. psittaci* strains of avian origin)

Chlamydia trachomatis (activities with high potential for droplet or aerosol production, large quantities or high concentrations, cultures of lymphogranuloma venereum (LGV) serovars, specimens known or likely to contain *C. trachomatis*)

Clostridium botulinum (activities with high potential for aerosol or droplet production, large quantities or high concentrations)

Coccidioides immitis, *C. posadasii* (sporulating cultures, processing environmental materials known or likely to contain infectious arthroconidia, experimental animal studies involving exposure by the intranasal or pulmonary route)

Corynebacterium diphtheriae ~~(HICPAC)~~

Coxiella burnetii (inoculation, incubation, and harvesting of embryonated eggs or cell cultures; experimental animal studies, animal studies with infected arthropods, necropsy of infected animals, handling infected tissues)

Crimean-Congo haemorrhagic fever virus

Cytomegalovirus, human (viral production, purification, or concentration)

Eastern equine encephalomyelitis virus (EEEV) (clinical materials, infectious cultures, infected animals or arthropods)

Ebola virus

Epstein-Barr virus (viral production, purification, or concentration)

Escherichia coli, shiga toxin-producing only (aerosol generation or high splash potential)

Flexal virus

Francisella tularensis (suspect cultures—including preparatory work for automated identification systems, experimental animal studies, necropsy of infected animals, high concentrations of reduced-virulence strains)

Guanarito virus

Haemophilus influenzae, type b ~~(HICPAC)~~

Hantaviruses (serum or tissue from potentially infected rodents, potentially infected tissues, large quantities or high concentrations, cell cultures, experimental rodent studies)

Helicobacter pylori (homogenizing or vortexing gastric specimens)

Hemorrhagic fever -- specimens from cases thought to be due to dengue or yellow fever viruses or which originate from areas in which communicable hemorrhagic fever are reasonably anticipated to be present

Hendra virus

Hepatitis B, C, and D viruses (activities with high potential for droplet or aerosol generation, large quantities or high concentrations of infectious materials)

Herpes simplex virus 1 and 2 ~~(HICPAC)~~

Herpesvirus simiae (B-virus) (consider for any material suspected to contain virus, mandatory for any material known to contain virus, propagation for diagnosis, cultures)

Histoplasma capsulatum (sporulating mold-form cultures, propagating environmental materials known or likely to contain infectious conidia)

Human herpesviruses 6A, 6B, 7, and 8 (viral production, purification, or concentration)

Influenza virus, non-contemporary human (H2N2) strains, 1918 influenza strain, highly pathogenic avian influenza (HPAI) (large animals infected with 1918 strain and animals infected with HPAI strains in ABSL-3 facilities, loose-housed animals infected with HPAI strains in BSL-3-Ag facilities)

Influenza virus, H5N1 - human, avian (~~HICPAC~~)

Junin virus

Kyasanur forest disease virus

Lassa fever virus

Legionella pneumophila, other legionella-like agents (aerosol generation, large quantities or high concentrations)

Lymphocytic choriomeningitis virus (LCMV) (field isolates and clinical materials from human cases, activities with high potential for aerosol generation, large quantities or high concentrations, strains lethal to nonhuman primates, infected transplantable tumors, infected hamsters)

Machupo virus

Marburg virus

Measles virus (~~HICPAC~~)

Monkeypox virus (experimentally or naturally infected animals)

Mumps virus (~~HICPAC~~)

Mycobacterium tuberculosis complex (*M. africanum*, *M. bovis*, *M. caprae*, *M. microti*, *M. pinnipedii*, *M. tuberculosis*) (aerosol-generating activities with clinical specimens, cultures, experimental animal studies with infected nonhuman primates)

Mycobacteria spp. other than those in the *M. tuberculosis* complex and *M. leprae* (aerosol generation)

Mycoplasma pneumoniae (~~HICPAC~~)

Neisseria gonorrhoeae (large quantities or high concentrations, consider for aerosol or droplet generation)

Neisseria meningitidis (activities with high potential for droplet or aerosol production, large quantities or high concentrations)

Nipah virus

Omsk hemorrhagic fever virus

Parvovirus B19 (~~HICPAC~~)

Prions (bovine spongiform encephalopathy prions, only when supported by a risk assessment)

Rabies virus, and related lyssaviruses (activities with high potential for droplet or aerosol production, large quantities or high concentrations)

Retroviruses, including Human and Simian Immunodeficiency viruses (HIV and SIV) (activities with high potential for aerosol or droplet production, large quantities or high concentrations)

Rickettsia prowazekii, *Orientia (Rickettsia) tsutsuagmushi*, *R. typhi* (*R. mooseri*), Spotted Fever Group agents (*R. akari*, *R. australis*, *R. conorii*, *R. japonicum*, *R. rickettsii*, and *R. siberica*) (known or potentially infectious materials; inoculation, incubation, and harvesting of embryonated eggs or cell cultures; experimental animal studies with infected arthropods)

Rift valley fever virus (RVFV)

Rubella virus (~~HCPCAC~~)

Sabia virus

Salmonella spp. other than *S. typhi* (aerosol generation or high splash potential)

Salmonella typhi (activities with significant potential for aerosol generation, large quantities)

SARS coronavirus (untreated specimens, cell cultures, experimental animal studies)

Shigella spp. (aerosol generation or high splash potential)

Streptococcus spp., group A (~~HCPCAC~~)

Tick-borne encephalitis viruses (Central European tick-borne encephalitis, Far Eastern tick-borne encephalitis, Russian spring and summer encephalitis)

Vaccinia virus

Varicella zoster virus (~~HCPCAC~~)

Variola major virus (Smallpox virus)

Variola minor virus (Alastrim)

Venezuelan equine encephalitis virus (VEEV) (clinical materials, infectious cultures, infected animals or arthropods)

West Nile virus (WNV) (dissection of field-collected dead birds, cultures, experimental animal and vector studies)

Western equine encephalitis virus (WEEV) (clinical materials, infectious cultures, infected animals or arthropods)

Yersinia pestis (antibiotic resistant strains, activities with high potential for droplet or aerosol production, large quantities or high concentrations, infected arthropods, potentially infected animals)

* ‘Large quantities or high concentrations’ refers to volumes or concentrations considerably in excess of those typically used for identification and typing activities. A risk assessment must be performed to determine if the quantity or concentration to be used carries an increased risk, and would therefore require aerosol control.

** ‘activities with high potential for aerosol generation’ include centrifugation

Appendix E: Aerosol Transmissible Disease Vaccination Recommendations for Susceptible Health Care Workers (Mandatory)

Vaccine	Schedule
Influenza	One dose annually

Measles	Two doses
Mumps	Two doses
Rubella	One dose
Tetanus, Diptheria, and Acellular Pertussis (Tdap)	One dose, booster as recommended
Varicella-zoster (VZV)	Two doses

Source: California Department of Public Health, Immunization Branch
Immunity should be determined in consultation with ~~current CDC and CDPH~~
~~guidelines~~ *Epidemiology and Prevention of Vaccine-Preventable Diseases.*

Appendix F: Sample Screening Criteria for Work Settings Where No Health Care Providers Are Available (non-mandatory)

This appendix contains sample criteria to be used by non-medical employees for screening purposes in settings where no health care providers are available. Coordination with local health departments, including TB control programs may be necessary for the success of this referral policy. Employees should be instructed in how clients' privacy will be maintained during screening procedures.

1. For screening a coughing client with potential TB – privately ask the person
 - a. if he/she has had a cough for more than three weeks.
 - b. if, in addition to cough, he/she has had one or more of the following clinical symptoms of TB disease:
 - Unexplained weight loss (>5lbs)
 - Night Sweats
 - Fever
 - Chronic Fatigue/Malaise
 - Coughing up blood

A person who has had a cough for more than three weeks and who has one of the other symptoms in b. must be referred to a health care provider for further evaluation, unless that person is already under treatment. Consider referring a person with any of the above symptoms, if there is no alternative explanation.

2. In addition to TB, other vaccine preventable aerosol transmissible diseases, including pertussis, measles, mumps, rubella (“German measles”) and chicken pox should be considered when non-medical personnel screen individuals in non-health care facilities. The following is a brief list of some findings that should prompt referral to a health care provider for further evaluation when identified through a screening process:

- Severe coughing spasms, especially if persistent; coughing fits may interfere with eating, drinking and breathing
- Fever, headache, muscle aches, tiredness, poor appetite followed by painful, swollen salivary glands, one side or both sides of face under jaw
- Fever, chills, cough, runny nose, watery eyes associated with onset of an unexplained rash (diffuse rash or blister-type skin rash)
- Fever, headache, stiff neck, possibly mental status changes

3. Any clients who exhibits any of the above described findings and reports contact with individuals known to have any of these transmissible illnesses in the past 2-4 weeks, should be promptly evaluated by a health care provider.

4. Health officials may issue alerts for community outbreaks of other diseases. They will provide screening criteria, and people must be referred to medical providers as recommended by the health officer.

Appendix G: Information for Respirator Fit-Test Screening (Mandatory if employer does not provide annual fit-test)

Respirators are an important means of reducing your exposure to infectious aerosols. Air purifying respirators provide a barrier to prevent health care workers from inhaling *Mycobacterium tuberculosis* and other pathogens. The level of protection a respirator provides is determined by the efficiency of the filter material and how well the facepiece fits or seals to your face.

Cal/OSHA regulations require that you be provided with a fit-test at the time of initial fitting, whenever a different size, make, model or style of respirator is used, and whenever you report a change in physical characteristics that may affect fit, such as major dental work, facial surgery or injury, or a change in weight.

Fit tests must also be repeated periodically, because people are not always aware of facial changes that may have affected the fit of the respirator. Generally, Cal/OSHA regulations require that fit-tests be repeated annually. The aerosol transmissible disease regulation permits employers to lengthen this interval to every two years, for employees who are not exposed to high hazard procedures, such as bronchoscopies. However, if you believe that you need another fit-test to ensure that the respirator is fitting you correctly, you may request an additional fit-test, and your employer will provide it.

A respirator will not protect you if it does not fit, and if it is not worn properly. In addition to fit-testing, it is important for you to be aware of the size, make, model and style of respirator that fits you, and to understand and practice how to put the respirator on and take it off. It is particularly important to properly place the straps, and in some models, to adjust the straps and adjust the nose piece, so that it forms a snug seal on your face. During your annual training, you will be shown how to use a respirator.

Screening Questions (Answer Yes/No)

Have you had recent major dental work, facial injury or facial surgery since your last fit-test?

Have you had a significant weight gain or loss since your last fit-test?

Do you want to be provided with an additional fit-test for your current respirator?

Name

Date

Employee ID number

Date of fit-test (if provided)

SUMMARY AND RESPONSE TO COMMENTS

SUMMARY AND RESPONSE TO WRITTEN AND ORAL COMMENTS

Roger Richter, Senior Vice President Professional Services, California Hospital Association (CHA), oral comments and written comments dated August 21, 2008.

Comment #RR1: The commenter commended Division staff for convening the advisory committee meetings, and for their responsiveness during the process. The hospital industry is pleased that respirator fit-testing requirements are to be permitted to be biannual until 2014 for certain hospital workers and the industry believes that based upon risk assessment, that biannual fit-testing can provide for more than an equivalent level of worker safety.

Response: The Board appreciates the feedback on the advisory process, and the hospital industry's support for the temporary biennial fit-testing option for certain hospital workers.

Comment #RR2: The hospital industry is pleased with Appendix B, the Alternative Respirator Medical Evaluation and its succinct structuring of pertinent information.

Response: The Board thanks the CHA for its support of Appendix B.

Comment #RR3: For compliance purposes, the term, "controlled substance release," in Section 5199(a)(1)(B) as opposed to the term, "uncontrolled substance release," should be referenced to Section 5192 of Title 8.

Response: The proposed standard includes a reference to Section 5192 of Title 8 for the term "uncontrolled substance release." The definition of "uncontrolled release" in Section 5192 has been in use for fifteen years, and is the subject of federal and state interpretations. The term "controlled release" does not appear in the ATD standard or in Section 5192. As explained in the ISOR, the use of this term is to identify employees who may be exposed to persons arriving from the scene of an intentional or unintentional release of biological agents, and who may bring contaminants with them on their clothing or persons. Therefore the Board believes that no change is necessary.

Comment #RR4: The definition in subsection (a)(2)(B) for "outpatient medical specialty practices whose policy is not to diagnose or treat ATDs" is ambiguous; the definition would benefit from specificity on which types of outpatient services are included or excluded.

Response: A definition of "medical specialty practice" is proposed to be added to subsection (b). Subsection (a)(2)(B) exempts from this standard outpatient employers, whose operation fits within the definition of medical specialty practices, have a policy not to diagnose or treat ATDs, and implement effective screening procedures.

Comment #RR5: The definition of "exposure incident" in subsection (b) should also require an investigation of the exposure and then should require an evaluation only if this screening investigation indicates the need for an evaluation; this screening should include a reference to the immunity of the exposed employee. Medically determined or documented immunity to the disease in question should mean that the exposed individual requires no additional follow-up.

Response: The Board agrees that the points raised in the comment are legitimate issues to be included in evaluation of exposure incidents, but believes that these issues are more properly addressed in the procedures for exposure incidents, included in subsection (h)(6), rather than in the definition. The purpose of the definition of an “exposure incident” is to clarify when an exposure investigation is to be initiated. Because determination of an individual employee’s immunity or need for medical follow-up is a medical issue, and involves confidential medical information, subsection (h)(6) separates the evaluation of exposure from the medical evaluation of the exposed employee. To clarify the difference between the exposure evaluation and medical evaluation, the term “medical” has been inserted into subsection (h)(6)(C)3.

Comment #RR6: The definition of “referring employer” in subsection (b) should clearly state that general acute care inpatient hospitals are not included.

Response: The definition has been changed by adding this sentence: “General acute care hospitals are not referring employers.”

Comment #RR7: Subsections (c)(4) and (e)(5)(B) regarding communication of disease status of referred patients to employees and other employers are problematic because of strict Health Insurance Portability and Accountability Act (HIPAA) and other confidentiality regulations. Communication and contact regarding some reportable diagnosed diseases, such as TB and measles, are handled by the health department.

Response: HIPAA and other confidentiality regulations were written so as not to pose obstacles to the protection of public health, and the provisions of these laws for health information privacy should be viewed from this context. The intent of the communication components of the ATD standard is to convey only that information necessary for post exposure evaluation and treatment. In addition, this proposal specifies that information should be communicated without communicating the name of the source patient. (A more complete discussion of California medical privacy requirements and HIPAA requirements is contained in several memos from DOSH staff attorney Allyce Kimerling in the rulemaking file). As to the second part of the comment, a change has been made to subsection (c)(4) to clarify the role of communication between the employer and the local public health officer.

Comment #RR8: Subsection (c)(7)(I) needs clarification on the extent of employee participation in reviewing the effectiveness of the employer’s procedures.

Response: Subsection (c)(7) lists the topic areas that referring employers must address in their training program. Subsection (c)(7)(I) is meant to train employees on how they can participate in the review of the employer’s infection control procedures. The review, and employee involvement in the review, is required by subsection (c)(8). Each employer’s review process will be different, but all are required to be effective. To clarify that this training element relates to the requirement in subsection (c)(8), a modification is proposed to subsection (c)(7)(I) to reference the procedures in (c)(8). A modification is also proposed for subsection (c)(8) to provide more specific information on requirements for employee participation in the review of the employer’s procedures.

Comment #RR9: Subsection (c)(7)(J) on training should recognize that for many modern forms of training such as computer-based training, the person conducting the training may not be

immediately available for interactive questions and answers. It should be permissible for contact information to be provided for a knowledgeable person who can be contacted within 72 hours after the training is completed.

Response: The Board recognizes that it is not always practical to have in-person training sessions led by a knowledgeable trainer and that computer and other training methods are frequently used. The requirement for interactive questions and answers is intended to assure that the training content that is provided to employees is understood within the context of the specific work activities of the employees. The opportunity for interactive questions is also meant to prevent an employee from misunderstanding subsequent material in the training because the question was not answered. The requirement for interactive questions and answers is also intended to ensure that the employee can pose the question before the employee forgets to do so. Also, in group training sessions, a question one person asks may represent questions others may share, but not ask. On the other hand, permitting answers via e-mail, phone, an in-person discussion or other mechanism by a designated knowledgeable individual may provide more consistent answers. It may also provide a mechanism for collecting information the employer can use in revising training. In addition, some employees may feel more comfortable asking questions outside of a group setting. To balance these concerns, the Board has proposed a modification of subsection (i), to apply to situations in which training is not provided by a knowledgeable in-person trainer. This would permit a mechanism for interactive questions in which questions submitted would be answered by a knowledgeable person within 24 hours of the end of the session.

Comment #RR10: There is no value to the subsection (d)(2)(D) requirement for listing all assignments or tasks requiring personal or respiratory protection equipment ahead of time since the trigger for use of the protection is the identification of a patient with an airborne or droplet transmissible disease and rooms/areas are required to be posted with warnings to employees about required PPE. Training of employees to recognize these postings and the appropriate use of the PPE is the key activity, and these requirements are elsewhere in the standard. So identifying ahead of time each specific task employees could perform that might require PPE is not necessary.

Response: The requirement in the Exposure Control Plan (Plan) to list the tasks or assignments requiring the use of PPE or respirators is intended to identify what assignments or tasks would require their use rather than predetermining locations for their use. In a large institution, this may be done by units, or assignment categories (such as respiratory therapy), as appropriate. This requirement is intended to assure that the employer has assessed procedures and identified the ones that would require personal protective equipment and/or respiratory protection, and recorded them in the Plan, so that the equipment and support activities such as training or fit-testing will be provided. This does not require the employer to restrict the use of rooms on the basis of periodic use of protective equipment, or to record each use of a room on that basis. This requirement would not preclude a procedure for posting a room for the type of protections that employees are to use. Consequently, the Board believes that a modification of this subsection is not necessary.

Comment #RR11: In most counties, adequate supply of personal protective equipment is under the control of the county public health officer for use in foreseeable emergencies and surge situations, so the requirement in subsection (d)(2)(M) for employers to ensure this adequacy of

PPE supply should be limited to normal operations and an explanation of how the hospital links to the county plan.

Response: This requirement was intended to address how employers would plan to obtain supplies of essential equipment during normal operations, foreseeable emergencies, and surge situations, not necessarily to require employers to maintain excessive individual stockpiles. Some supplies need to be available on-hand, to cover normal operations and short-term emergencies that do not activate local or regional surge plans. The Board agrees that a prolonged surge situation may exceed the capacity of an individual employer's planning and resources, and acknowledges that some of this function has been delegated to local and regional planning agencies. The employer needs to assess how to cover an initial period before local or regional area surge supplies can be located and distributed, and how access to local and regional stockpiles will be accomplished. For this reason, requirements regarding surge in subsection (d) have all been relocated to subsection (d)(2)(Q) which would require that the plan explain how the employer will interact with the local and regional emergency plan.

Comment #RR12: Subsection (e)(1)(A) incorrectly directs employers to use the CDC TB Guidelines for determining airborne precautions for all diseases while these guidelines are specific to TB and do not reference other airborne communicable diseases. Instead, the following rewording is suggested, "Airborne, droplet, and contact precautions shall be in accordance with Guideline for Isolation Precautions. Airborne precautions specific to tuberculosis shall be in accordance with the Guideline for preventing TB."

Response: A modification to this subsection is proposed to require that control measures to minimize airborne, droplet or contact transmission of ATPs be adopted as necessary for the specific disease, pathogen or condition, and as listed in Appendix A, which identifies diseases requiring airborne infection isolation or droplet precautions. Droplet and contact precautions are described in the CDC Guideline for Isolation Precautions. However, this document references the Guideline for Preventing the Transmission of *Mycobacterium Tuberculosis* for further explanation of airborne infection isolation, and notes that the explanation of these controls may be applied to other diseases transmitted by the airborne route. For this reason, the standard refers to the TB publication to further describe airborne precautions.

Comment #RR13: Subsection (e)(3) is too vague about which contractors with temporary or contract employees it is necessary to provide information about infectious disease hazards, when in fact such information dissemination needs to be based on risk of exposure to these employees.

Response: A modification to the language of this subsection is proposed to require providing information to contractors whose employees may be "reasonably anticipated to have occupational exposure" to infectious disease hazards.

Comment #RR14: For consistency, subsection (e)(5)(D)4 should reference maintenance of High Efficiency Particulate Air (HEPA) filters associated with Ultraviolet Germicidal Irradiation (UVGI) systems to the Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings. CHA assumes this section refers to HEPA filtration of air from an AIIR that would enter a room receiving recycled air or HEPA filtration for exhaust air. CHA recommends replacing the first two sentences with "Engineering controls (including any HEPA filters for UVGI) shall be used, maintained, inspected and controlled in accordance with

Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings.”

Response: The Board believes that it is important to specifically include the information on the maintenance of HEPA filters currently provided in subsection (e)(5)(D)4. These filters are used to provide supplemental air cleaning technology. UVGI is a separate form of air cleaning technology that is still undergoing considerable development and research. For this reason, the Board cannot, at this time, establish specific requirements for its use, but instead refers employers to the discussion of UVGI in the referenced guideline.

Comment #RR15: Health care laboratories that are certified by the College of American Pathologists (CAP) should be exempt from the requirements of subsection (f) because CAP certification addresses laboratory worker safety issues and provides equivalent protection.

Response: No requirement in subsection (f) is in conflict with the requirements for CAP certification. To the extent that meeting the requirements for CAP certification fulfills all the requirements of subsection (f), there would be no additional obligations upon health care laboratories. However, this subsection is necessary for all labs, CAP certified or not, in order to create enforceable requirements. Audits by certifying agents cannot be used in place of the Labor Code mandate for the Division to respond to complaints and accidents or for the Board’s responsibility to adopt regulations necessary to protect the health of employees.

Comment #RR16: Subsection (g)(3)(B) should read “The employer shall provide a respirator at least as effective as a powered air purifying respirator (PAPR)” because there may be other appropriate respirators available now, or in the future.

Response: A change has been made to the subsection allowing respirators providing equivalent protection to the PAPR.

Comment #RR17: For the examples of respirator use under subsection (g)(4), it should be emphasized that a N95 respirator be used.

Response: In subsection (g)(3)(A) the proposed standard clearly permits the use of an N95 respirator, where it will provide sufficient protection. In order to coordinate those requirements with subsection (g)(4), which specifies the circumstances in which respirator use is required, a phrase has been inserted into subsection (g)(4) stating that “a respirator, selected in accordance with subsection (g)(3) and Section 5144...” shall be used.

Comment #RR18: CHA supports the fit-testing requirements recommended in this policy and the exceptions that are part of the standard.

Response: The Board appreciates the support of CHA for the respirator fit-testing requirements of this standard.

Comment #RR19: Subsection (h) language should be consistent with workers compensation program language. Rollouts over a reasonable time period should be permitted for new employees and existing employees. CHA suggests a one-year phase in.

Response: Precautionary removal provisions of this subsection apply to a period when an exposed employee is not yet eligible for workers compensation benefits (i.e., during a possible incubation period of a disease when the employee is potentially infectious to others but is not sick), so language equivalence with the workers compensation program is not appropriate. Precautionary removal specifically does not apply to a period of time during which the employee is unable to work, other than for reasons of precautionary removal, such as when the employee is sick with an occupational illness. The implementation date of the vaccination requirements of this subsection is proposed to be extended by a year after the effective date of the regulation.

Comment #RR20: In the first sentence of subsection (h)(1), CHA recommends the term “medical surveillance” be replaced with the term “screening measures” to avoid conflict with the way the term surveillance is generally understood.

Response: Throughout the standard, the Board has substituted the term “medical services” for “medical surveillance,” except where the term is used to refer to the surveillance program for tuberculosis infection. The term “assessment” is used to refer to individual TB tests or other TB screening measures.

Comment #RR21: For subsection (h)(5)(D), if an employee declines a vaccination initially but later wants to accept it, the request needs to be in writing.

Response: The Board has made the requested change.

Comment #RR22: Subsection (h)(6)(B) establishes a 24 hour time period within which an analysis of an exposure incident must occur and a 48 hour time period within which to notify employees who had significant exposure. The 24 hours should be changed to “a period of time which is prudent and reasonable” because often the exposure incident would be to a reportable disease for which the health department has jurisdiction and consequently the employer’s infection control and occupational health personnel must coordinate with the health department. Sometimes 48 hours is too long and sometimes it is not reasonable, largely because of weekends, so the standard should list exceptions. Specific time intervals shouldn’t be used unless the California Department of Health requires them.

Response: This subsection has been changed so that the timeframe within which the employer is to notify other employers and is to initiate an investigation to identify exposed employees is to be based on the timeframe necessary to provide appropriate intervention, but in no case shall it be later than 72 hours following the report to the local health officer. The issues affecting the appropriate timeframe include effective medical intervention to prevent disease or mitigate the disease course and measures to prevent further disease transmission. In addition, the timeframe must be short enough to initiate an effective investigation to identify exposed employees. A note to this subsection has been added to provide further clarification. For communicating about exposure incidents to exposed employees, the period is proposed to be lengthened to a maximum of 96 hours following employer awareness of the potential exposure. As the CHA suggested, variability in timeframe is necessary because sometimes 24 or 48 hours is unnecessarily short, and sometimes it is too long, depending on the disease. However, delays of more than a few days can adversely affect the success of investigations of exposure incidents, and may lead to the exclusion of some employees from post-exposure follow-up.

Comment #RR23: Appendix A's linking via footnote #1 of Airborne Infectious Diseases/Pathogens of Airborne infection isolation including droplet precautions is incorrect. CHA recommends using the same List and same language as the most recent CDC Guidelines for Isolation Precautions (2007).

Response: The footnote in Appendix As has been removed. Additional changes have been made in Appendix A to make its nomenclature consistent with the published version of the referenced guidelines.

Comment #RR24: Most employees do not understand many of the technical terms for different types of respirator utilized in Appendix B. It would be beneficial if Cal/OSHA provided a diagram/definitions which health care facilities can access via Cal/OSHA's website to educate workers.

Response: The Board thanks the CHA for the suggestion on increasing the useful information on respiratory protection terminology that should be added to the Division's web site. The Division has indicated that it is preparing a number of educational materials and implementation aids to help employers if the proposal is adopted.

Meanwhile, some resources currently available on this subject, include:

Page 9 of the Division's publication, *Respiratory Protection in the Workplace*

[http://www.dir.ca.gov/dosh/dosh_publications/respiratory.pdf], includes a partial glossary of respirator terminology as does the Cal/OSHA respiratory protection standard 8CCR 5144 definition section [<http://www.dir.ca.gov/Title8/5144.html>]. The CDC and Federal OSHA also have useful materials, for example, *TB Respiratory Protection Program In Health Care Facilities* [<http://www.cdc.gov/niosh/99-143.html#step2>] and the OSHA Respirator Quick Card [<http://www.osha.gov/Publications/3280-10N-05-english-06-27-2007.html>]

Bill Kojola, Industrial Hygienist, American Federation of Labor and Congress of Industrial Organizations, by letter dated August 15, 2008.

Comment #BK1: The AFL-CIO is pleased that California is proposing a workplace standard to protect workers against aerosol transmissible diseases. The proposed standard takes the most effective approach, which is a comprehensive standard incorporating airborne and droplet exposures to a wide range of infectious agents.

Response: The Board thanks Mr. Kojola for his comments.

Comment #BK2: The exclusion for dental offices (a)(2)(A) makes sense where these offices do not perform dental procedures on known or suspected ATD cases. However the screening procedures need to be covered in order to ensure that employers implement them and train employees. Also, there is no evidence that physicians have the knowledge and experience to determine whether or not a given dental procedure performed on a patient identified through the screening procedures poses an ATD risk to employees under subsection (a)(2)(A)3. If procedures are to be performed on a patient with an ATD, the employees should be protected by the requirements of the standard.

Response: The Board agrees with the commenter that it is necessary to ensure that the screening procedures are implemented and that employees are trained. However inclusion of these operations under Section 5199 is not necessary to accomplish this purpose. Instead, language has been added to subsection (a)(2)(A) to ensure that screening procedures and training of employees will be accomplished in accordance with the Injury and Illness Prevention Program regulation, Section 3203.

The Board further agrees that a physician may not be able to determine whether a given dental procedure poses a risk of ATD transmission to dental employees. The proposed language has been changed to condition the exemption of a dental office from application of this standard on a policy of not performing dental procedures on patients who had been screened as potentially having a transmissible ATD, unless a physician determines that the patient does not have an ATD.

Comment #BK3: The exclusion for medical specialty practices in subsection (a)(2)(B) does not ensure that the screening procedures required by the exclusion will be conducted. Including these workplaces within the scope of the standard is the only way to ensure that employers implement screening procedures and to ensure that employees are trained.

Response: The Board agrees with the commenter that it is necessary to ensure that medical specialty practices that do not come within the scope of this section conduct appropriate screening procedures. However, inclusion of these operations in Section 5199 is not necessary to accomplish this purpose. Instead, language has been added to subsection (a)(2)(B) to ensure that screening procedures and training of employees will be accomplished in accordance with the Injury and Illness Prevention Program regulation, Section 3203.

Comment #BK4: The commenter is pleased to see that California is proposing to include within the definition of Airborne Infectious Disease (AirID) “novel and unknown pathogens.” The commenter believes that treating novel and unknown pathogens as potentially transmitted by airborne means is an appropriate precautionary approach and is necessary to protect exposed workers. The commenter also supports the note that explicitly includes pandemic influenza strains as novel pathogens.

Response: The Board thanks Mr. Kojola for his support of the proposed standard.

Comment #BK5: The qualifying phrase in subsection (c)(5)(C) would limit the circumstances in which a referring employer would be required to provide employees with respiratory protection when entering a room or area in which a person is waiting for referral to those circumstances in which the person “is not compliant with source control procedures.” This condition is vague and difficult to interpret, and is insufficiently protective of worker health. The commenter asked what the criteria are for determining if a person is compliant. The standard should include a requirement for the use of respiratory protection whenever a worker enters the room or area of a person awaiting referral, with no exception.

Response: The standard envisions that the main methods referring employers will use for controlling exposures to airborne infectious diseases are early identification of possible cases and limiting the amount of time potentially infectious individuals remain in the work place. Additional protection is afforded by separating the individual and providing ventilation, where

feasible. The standard requires most employers to develop effective source control measures, including how people will be informed about those measures. These steps will result in increased compliance with source control measures. Training of supervisors and employees in source control measures which the standard requires will help them to determine whether a patient is compliant. Where the patient is non-compliant, respirators must be used if it is feasible. For employees in homeless shelters and other referring employer environments, the combination of the methods described above will substantially reduce risk without mandating the use of respirators in all situations.

Comment #BK6: To maximize the protection of employees who will enter areas where persons are awaiting referral, the standard should require that the referred person be provided with a procedure mask, as part of the source control measures.

Response: Source control measures, as recommended by the CDC, permit the use of masks or, as an alternative, tissues and hand hygiene materials to control respiratory secretions. In some circumstances a patient cannot use a mask. The proposal leaves it to the institution to determine the most effective means for controlling respiratory secretions in that setting. This determination would be reviewed annually, with the participation of employees.

Comment #BK7: The language in subsection (c)(6)(B) that would require that referring employers provide medical services in accordance with subsections (h)(6) through (h)(9) is too limited in requiring the services only for RATD cases or suspected cases. The commenter states that diseases reportable under Title 17 do not include avian influenza, SARS, monkey pox and novel and unknown pathogens. There is no scientific reason to exclude “unreportable” diseases from procedures for exposure incidents.

Response: Title 17, section 2500, requires reporting of human cases of avian influenza, and SARS. Title 17 is regularly reviewed by the state health department and local health officers to ensure that it is up-to-date. Monkey pox is an extremely rare disease in the U.S. Title 17 also requires reporting of the occurrence of any “unusual disease” and “outbreaks” of any disease. The Board believes that this sufficiently covers novel and unknown pathogens.

In creating this standard, the Division attempted to work within the current public health structure, which relies on the local health officer and the current system of communicable disease reporting. It is beyond the scope of the Board's authority to create a new mandate for local health officers.

Comment #BK8: The commenter supports the requirement in subsection (c)(7) that employees covered by this standard receive training at the time of initial assignment and at least annually thereafter. New language should be added requiring additional training when there are changes in the workplace or new information becomes available. It is important that workers have the new information as soon as possible.

Response: The Board agrees that changes in procedures or in the workplace that potentially affect employee exposures should require additional training, and language has been added to the proposed subsection.

Comment #BK9: Subsection (c)(7)(H), which requires training on vaccines, should be expanded to include training on treatment options such as antibiotics and antiviral drugs which may be used to protect workers after exposure incidents or as prophylaxis.

Response: The Board agrees that a requirement to provide information on how exposure incidents will be handled, which may include information on the use of prophylactic medications, should be included in the standard. Subsection (c)(7)(G) has been modified to include a requirement that employees be trained on the employer's procedures for providing employees with post-exposure evaluations. Providing information on vaccines is necessary to ensure that employees choose to participate in vaccination programs, unless the vaccine is not appropriate for them. Information on specific use of antibiotic or antiviral therapies is more appropriately given, if necessary, when there is a specific exposure. The information should be provided by a knowledgeable PLHCP who can assess the employee's specific medical circumstances.

Comment #BK10: The development of an exposure control plan is a necessary and critical function of the standard. The proposal places responsibility for the development of the plan on the employer but is silent on the sources of information and expertise that the employer should seek out in preparing the plan. Frequently workers and their unions represent rich and useful sources of information, knowledge and input that can assist the employer and development of the plan. The commenter therefore recommends requiring that employers involve workers and their unions in developing the plan.

Response: The Board agrees that the exposure control plan is an important tool in controlling employee exposures to ATDs, and that workers and their unions are a valuable resource in developing such a plan. The proposal as written allows the employer to develop the plan in any way that is appropriate to the work place, which may include consultations with employees and their representatives. Since most facilities will be modifying an existing infection control plan to comply with this standard, a requirement that employers go back to the beginning in developing a plan may lead to unnecessary implementation delays. The proposal does include language requiring the employer to consult employees at least annually as to how the plan is implemented in their work areas. This consultation should provide a mechanism for employees to be involved in reviewing the plan and ensuring that it is effective.

Comment #BK11: The commenter supports the requirement in subsection (d)(3) for annual review of the plan by the program administrator and employees regarding the effectiveness of the plan in their work area. Additional language should specifically require employers to actually modify the plan based upon the findings and employee input obtained in the annual review. Also, the proposal should include a requirement that the plan be modified whenever there is new information or circumstances that significantly impact on the health and safety of workers.

Response: The Board agrees that employers should be required to act on findings of the annual review, and language has been added to this subsection to require that deficiencies found be corrected. The language in subsection (d)(2)(P) has also been revised to clarify that the procedures for involving employees in the review of the plan be effective. The Board does not agree that is necessary to require in subsection (d)(3) that the plan be reviewed whenever there is new information or circumstances that impact on employee exposure. The current performance language, which requires that the employer's plan contain effective procedures for review,

permits the employer to review the plan as necessary. The requirement to review the plan at least annually does not prevent the employer, either on its own initiative or based on employee request, from reviewing the plan more frequently. In addition, subsection (d)(2)(J) requires that the plan include a procedure for evaluating exposure incidents and revising existing procedures to prevent further incidents.

Comment #BK12: The commenter supports the requirement in subsection (d)(4) that the exposure control plan be made available to employees and their representatives for examination and copying. The commenter supports adding a requirement establishing the maximum timeframe, preferably by the end of the next business day following a request. The commenter also suggests adding a requirement that the copy be provided to requesters at no cost to them.

Response: The Board agrees that the standard should incorporate a maximum timeframe for making the plan available. Language has been added to subsection (d)(4) and subsection (j)(4), the effect of which is to require the plan to be available for copying in accordance with Section 3204, which generally establishes a maximum timeframe of 15 days, and requires the employer to provide the first copy to a requestor at no charge, or to loan it to the requestor for copying.

Comment #BK13: The commenter supports the requirement in subsection (e)(1) to use feasible engineering and work practice controls to minimize exposure. Examples of engineering and work practice controls should be provided. Also subsection (e)(1)(A) should be rewritten to discuss types of engineering controls. The existing language relating to work practice controls should be placed in subsection (e)(1)(B). Existing subsections (e)(1)(B) and (e)(1)(C) would then be re-lettered. The personal protective equipment references should be removed from the context of the note about work practices currently attached to subsection (e)(1)(A). The commenter also suggests requiring personal protective equipment for employees who transport ATD cases or suspected cases.

Response: Subsection (e)(1) establishes a hierarchy of controls for ATP hazards. The primary methods of control are engineering controls and work practices. Although the commenter suggests separating engineering controls and work practices, particularly in the health care environment, these two methods of control work together. For example, early case identification and limiting contact with a potentially infectious patient is a work practice control, including placing the patient in a separate room or area. The separate room, and the ventilation provided to that room or area are engineering controls. For this reason, these two items are addressed together. When these control measures are not sufficient to control the hazards, then this section requires the use of personal protective equipment and respiratory protection. This hierarchy pertains to all operations, including transport of patients.

The purpose of subsection (e)(1)(A) is to reference two recognized sources of more specific information about airborne precautions and about droplet and contact precautions. The note is meant to give examples of work practice controls, and therefore the Board agrees with the commenter that the examples of using personal and respiratory protection should be removed, and the language of the note has been modified.

The purpose of subsection (e)(1)(B) is to address source control measures in the context of employers who are not referring employers. Source control, which consists of a combination of

work practices and engineering controls, is currently strongly supported by the CDC and other public health and infection control practitioners.

Employers whose employees transport ATD cases and suspected cases, in facilities and in vehicles, are required to comply with the general requirements of subsection (e)(1), including providing appropriate personal protective equipment. The purpose of subsection (e)(1)(C) is to specifically address the use of engineering controls such as barriers and air handling systems in the context of vehicle use.

Comment #BK14: The term “susceptible” should be removed from proposed subsection (e)(5)(B)2.e. which requires respirator use by all “susceptible” employees who enter an AIIR room or area where AirID cases or suspected cases are housed. The commenter states that the term “susceptible” is undefined and should be removed to avoid confusion. All workers who enter the room or area should be provided with respiratory protection, as well as other forms of PPE.

Response: Although, the term susceptible is defined in subsection (b), the Board agrees that removal of the term “susceptible” from this subsection will prevent any confusion about whether an employee needs to use a respirator when entering an airborne infection isolation room. Most AIIR use is in conjunction with suspect or confirmed TB, to which all people are considered susceptible. In addition, since vaccines are not 100 percent effective, it is prudent to require respirator use for all AIIR.

Language has also been added requiring that employers provide appropriate personal protective equipment.

Comment #BK15: The commenter supports the requirement in the exception to subsection (e)(5)(C) that when high hazard procedures are performed outside of airborne infection isolation rooms or areas, that all employees working in the room or area where the procedure is performed use respiratory protection. The commenter believes that this requirement should also include all necessary PPE.

Response: The Board agrees that personal protective equipment must be provided to anyone in the area where a high hazard procedure is performed. Language has been added to require that persons not performing the procedure be excluded from the area where these procedures are being performed, unless the person is provided with the PPE and respiratory protection required for persons performing the procedure.

Comment #BK16: The commenter disagrees with subsection (g)(3)(A) which requires that the minimum level of respiratory protection provided under this standard be at least as effective as an N95 filtering facepiece respirator. The commenter believes that the minimum level of protection should be a P100 filtering facepiece respirator equipped with an elastomeric facepiece seal. The commenter provided several articles that he believes raise questions about the effectiveness of N95 filtering facepiece respirators in protecting employees against infectious aerosols. (See Lee, 2008, Balazy, 2006, and Eninger, 2008).

Response: The Division has reviewed the referenced articles. Although these articles raise some question regarding the exact protection factor provided by N95 respirators against some sizes of particles, many questions remain. For example, it is not known what size particle must be

captured by the respirator filter in order to prevent infection, as many pathogens are presented in a droplet or droplet nuclei, rather than as a naked pathogen. At this time, the National Institute for Occupational Safety and Health and the Centers for Disease Control and Prevention, recommend the use of the N95 respirator. Studies have found that N95 respirators provide effective protection against a range of particle aerosols. (See, for example, Coffey 2004, Lawrence, 2006) In addition, the other control measures required by this standard, including limiting the amount of contact employees have with AirID cases and suspected cases, requiring the placement of AirID cases and suspected cases in specially ventilated rooms, and requiring additional controls for high hazard procedures provide a matrix of risk reduction measures that supplement the filtering capacity of respirators. Therefore the Board has not determined at this time that a higher level of respiratory protection is necessary, other than in the conditions specified in other portions of this standard.

Comment #BK17: The commenter supports the requirement in subsection (g)(3)(B) that a PAPR equipped with HEPA filters be provided to workers who perform high hazard procedures and work on cadavers. This requirement should be modified to permit the use of a respiratory protection device providing equivalent or better levels of protection, in order to permit the use of supplied air respirators or other respirators. Also, employers should be required to provide a PAPR to employees who have been determined to be medically incapable of wearing a filtering facepiece respirator but who are capable of wearing a PAPR.

Response: The Board agrees with the commenter that a respirator equivalent to a PAPR should be permitted, and language has been added to permit the use of respirators at least as effective as a PAPR with HEPA filters.

The issue of whether an employer should be required to provide a PAPR if a PLHCP determines that an employee cannot use an air-purifying respirator for medical reasons, but can use a PAPR, was discussed in the advisory meetings. Participants believed that while a PAPR may be a reasonable way to address a medical disqualification in some circumstances, it may not be appropriate, or it may not be feasible in others. For this reason, the Board does not think it is advisable to include a requirement in the standard that would apply to all circumstances. However, the Board notes that a PAPR when recommended by a PLHCP to address a medical issue, may be a reasonable and appropriate way to provide the employee with respiratory protection.

Comment #BK18: The commenter disagrees with the exception to subsection (g)(6)(B)3, that permits the repeat fit-testing interval to be increased to every two years until January 1, 2014, for employees who do not perform high hazard procedures. The commenter states that although the proposal mentions a NIOSH study that will provide information on appropriate fit-test intervals, there is no evidence available at this time that supports a fit-test interval longer than one year, and there is evidence that supports the requirement for annual fit-testing. Further, the commenter cites several studies that show that a respirator that has passed a fit-test for an individual worker provides better protection than one that has not (Lee 2004, Coffey 2004, Lawrence 2006).

The commenter also cites evidence in the OSHA record supporting annual fit-testing, and a letter from NIOSH Director John Howard, supporting an annual fit-test interval. The commenter disagrees that the issue of cost to employers of annual fit-testing should be a reason to increase

the fit-test interval, given the lack of scientific support for a longer interval. The commenter further states that this Cal/OSHA provision would be less effective than Federal OSHA.

Response: The Board agrees in part with this comment, and additional requirements pertaining to the biennial fit-test exception have been included in the proposed language. The Board agrees that initial and periodic respirator fit-testing are necessary to ensure that employees are issued respirators that can provide protection to the employee. The studies cited by the commenter do not actually address an appropriate fit-test interval. In the course of this rulemaking, the Division has received some evidence regarding fit-test intervals (Mendelsohn), and the relationship between training and fit-testing (MC Lee). Respirator fit-testing is currently an area of active research. The Board believes there is a need for scientific studies to determine how employees can be reliably provided with good-fitting respirators, including the reproducibility of fit-tests and the role of training in achieving a good fit.

This rulemaking proposal represents, in significant part, one manner in which the State of California is preparing for the threat of health care surge events, the most prominent example of which is the possibility of pandemic influenza.

The reality is that when a surge event arises, employees are called on to participate and do participate whether they are adequately protected or not from the consequences of exposure to the patients they care for. Therefore, it is in the interest of public health in general as well as the individual workers who will be involved in surge events to emphasize the kind of preparation needed to maintain employee health and safety during these events. Because respirator use is one of the most important forms of employee protection available in surges, maximizing the number of employees provided with fit-tested respirators is essential.

This requires identification, medical evaluation, training and fit-testing of all employees likely to need a respirator in the event of a surge. The temporary lengthening of the fit-test interval will have a direct and significant impact on the number of workers who can be maintained in a state of readiness at any given time and is essential to maximizing the preparedness of the health care industry to confront surge events. Without this lengthened interval, it is likely that significant numbers of employees who, under this proposal would be fit-tested and prepared for respirator use, will either not be provided a respirator in situations where one is necessary to protect the employee's health, or be provided a respirator without any fit-testing at all or any of the evaluation or training that go with fit-testing to assure that the respirator will protect them.

The language permitting a biennial fit-test for employees who do not perform high hazard procedures will sunset on January 1, 2014, requiring that by January 1, 2015, all respirator users have a fit-test within the previous 12 months.

In addition to this sunset language, the proposal has been amended to include a requirement that employers who provide biennial fit-tests provide fit-test screening during the year when a fit-test is not provided. This screening, included in Appendix G, explains the importance of proper respirator use and respirator fit, and describes conditions such as facial injury or surgery, major dental work, or significant weight change, that may change the fit of the respirator. Appendix G asks the employee to indicate if any of these conditions apply. In that case, the employer would be required to provide an additional fit-test. Appendix G also explains that an employee who wishes an additional fit-test will be provided one upon request.

The Board believes that the overall framework of the standard is the most effective approach to protecting employees from ATDs and that the standard, as proposed to permanently take effect, is at least as effective as existing federal requirements.

Comment #BK19: The commenter supports the activities required in subsections (h)(6)(A) and (h)(6)(B) in response to exposure incidents. These activities should not be restricted to diseases that are reportable under Title 17 of the California Code of Regulations, which the commenter states does not include avian influenza, SARS, monkeypox and novel or unknown pathogens. There is no scientific rationale for eliminating these diseases from requirements for exposure incidents.

Response: See response to comment #BK7.

Comment #BK20: The commenter believes that subsection (j)(4)(A) should include a requirement that employees and employee representatives be afforded access to all records, other than employee medical records, that are required to be maintained under this standard. Lack of access may hamper the ability of employees and their representatives to utilize their knowledge and expertise to advance safety and health measures in their workplace. The standard should include provisions establishing a deadline by which records are to be provided to a requester, such as by the end of the next business day. The records should be provided to employees and their representatives at no cost to them whenever they are requested.

Response: The Board agrees that access to records of program implementation, other than employee medical records, would enhance the ability of employees and their representatives to participate in reviewing and updating the employer's infection control procedures. The Board believes that Section 3204 establishes a reasonable framework for providing these records, including that the records be provided within 15 days of the request, and establishes a framework for either providing an initial copy of the record to the requester at no cost, or loaning the record for copying. Therefore language has been added to subsection (j)(4)(B) to require that access be provided to employees and their representatives in accordance with Section 3204.

Comment #BK21: A section should be added to address "housekeeping," to include such issues as disposal of infectious waste and patient-care equipment, and environmental cleaning and disinfection.

Response: Housekeeping, as described in this comment is important to controlling infectious disease; and the proposal and existing standards include a number of requirements that address this issue. Proposed subsection (c)(1) requires referring employers to establish, implement and maintain effective infection control procedures, which was originally envisioned to include cleaning and disinfecting. In response to this and other comments, an additional sentence has been added to clarify that these procedures include cleaning and disinfection of work areas, vehicles, and equipment that may become contaminated with ATPs and pose an infection risk to employees. An addition has also been made to subsection (d)(2)(E) to specify that cleaning and decontamination must be included in the written Exposure Control Plan. Subsection (e)(2) requires non-referring employers to have effective decontamination and cleaning procedures for work areas. In laboratories, subsection (f)(4)(G) (formerly (f)(3)(G)), requires decontamination and disinfection procedures. Most employers within the scope of this standard are also within the

scope of Section 5193, which contains specific housekeeping requirements to protect employees against contact with blood or other potentially infectious materials (OPIM). Additionally, Article 9 of Title 8 requires all employers to maintain workplaces in a clean and sanitary condition. Therefore, the Board does not believe there is a necessity to establish a separate housekeeping section in this proposal.

Comment #BK22: A subsection should be added regarding labels and signs to alert and warn employees about exposure potential related to equipment, objects, rooms or areas. This would assist in reducing exposure incidents and protecting workers from infection.

Response: The bloodborne pathogens standard, Section 5193, requires labeling of contaminated equipment and wastes, and the Board does not see a need to supplement this requirement in the proposed standard. In regards to the labeling or signage for areas in which there is a potential exposure, the Board believes there may be significant patient confidentiality issues in adopting a broad requirement for signage. Therefore, the proposed standard requires employers to include an effective means to communicate with employees regarding the infectious disease status of patients in the exposure control plan, or, in the case of referring employers, in their infection control procedures. These procedures must be reviewed at least annually with employees.

Annemarie Flood, President Elect, California Association of Professionals in Infection Control (APIC) Coordinating Council (CACC), electronic mail dated August 21, 2008.

Comment #AF1: CACC believes that the proposed requirement for the use of Powered Air Purifying Respirators (PAPRs) for high hazard procedures is not supported by existing data that demonstrates the existence of a hazard. CACC previously supplied Cal/OSHA with conversion rate data. There is also the concern that the PAPR because of the noise it produces, and the weight of the device, may interfere with patient and employee safety.

Response: Health care workers in California continue to experience TB conversions and develop active tuberculosis. A health care worker who contracts TB infection has an estimated ten percent risk of developing active TB during his or her lifetime, and for some individuals, this risk may be higher. To reduce this risk, many health care workers who develop infection are placed on antibiotic therapy that involves one or more drugs that may have significant side effects. During the advisory process, a nurse who contracted active TB as a result of an exposure in a LA area hospital, spoke about his experience working in an ICU, and the effect developing infectious TB had on his life. The California Labor Code requires the Board to adopt regulations that are necessary to protect employees against health and safety hazards. In 2007, over 2700 TB cases were reported through the public health system in California. Each reported case may expose dozens of health care workers to infection.

In addition, TB in California is increasingly likely to be drug resistant. The CDPH Report on Tuberculosis in California, 2007, states that the *“frequency of resistance to isoniazid (INH), one of the primary drugs used to treat TB, rose to 11 percent in 2007 (Table 45) from less than 10 percent in 2006 (Table 45). Among those with a prior episode of TB, the frequency of INH resistance was nearly 18 percent (Table 38). Where INH resistance exceeds four percent, the recommendation is to start all TB cases on an initial four drug regimen. In 2007, over 88 percent of cases began TB treatment with a four drug regimen (Table 26).*

“California continues to report the largest number of multidrug resistant (MDR; resistant to at least isoniazid and rifampin) TB cases in the nation. Between 27 and 39 cases of MDR TB were reported per year in California between 2003 and 2007 (Table 43, Figure 13). During this five year period, MDR TB cases were reported in 25 (41 percent) of California’s 61 local health jurisdictions, including several rural and smaller health jurisdictions where experience in treating MDR TB may be limited. Although the overall proportion of MDR TB cases remains low (1.3 percent in 2007), the potential consequences of these deadly strains of TB to the patient and to the public can be costly in terms of human mortality, transmission of disease, and resource requirements. Three cases of the most severe form of drug resistance, termed extensively drug resistant TB (XDR TB) were reported between 2003-2007 (data not shown). XDR TB is defined by the World Health Organization as resistance to isoniazid and rifampin, as well as at least one fluoroquinolone and any of the second-line injectable agents, amikacin, kanamycin, or capreomycin.”

As noted in the ISOR, the requirement for the use of PAPRs for high hazard procedures on AirID cases and suspected cases is based in part on the recommendations of the American College of Chest Physicians and the American Association for Bronchology. In addition, tuberculosis researchers have documented significant risk to health care providers during high hazard procedures. Some of this research is summarized in a communication from Kevin P. Fennelly, Transmission of Tuberculosis During Medical Procedures (Fennelly, 1997). In a 1998 article, Fennelly recommended the use of PAPRs during autopsies and bronchoscopies for TB, and stated, “Bronchoscopic procedures and autopsies on patients with possible tuberculosis have been associated with a high risk of transmission of tuberculosis and estimates of 250 to over 1000 infectious particles produced per hour.” He also summarized the successful experience with PAPRs at National Jewish hospital, saying, “We have little difficulty in the use of only three of these units at our facility; this allows for use by a bronchoscopist and one or two assistants. These devices are quite comfortable for procedures, and patients seem to become accustomed to their use quite easily. In my opinion, PAPR hoods are the most sophisticated personal respiratory protective devices which are appropriate for health care settings.” (Fennelly, 1998)

The requirement to use PAPRs for high hazard procedures is not only based upon tuberculosis. Although there are no current reports of Severe Acute Respiratory Syndrome (SARS), during the SARS outbreak in 2002-2003, high hazard procedures were significantly associated with the development of disease in health care workers. A study of critical care nurses who were exposed to SARS patients in a Toronto hospital in March 2003, found that nurses who performed intubation and suctioning before intubation were at increased risk of developing SARS, and that two nurses who performed these procedures even though they used N95 respirators, contracted SARS (Loeb). Similarly, nine health care workers in Toronto in April 2003 who were exposed to a SARS patient who was intubated, developed illnesses consistent with the definition of a SARS probable case, and two developed atypical symptoms, despite the use of N95 respirators and the placement of the patient in an airborne infection isolation room (Ofner, 2003).

The requirement to use PAPRs is also based upon research showing that high hazard procedures may increase the generation of infectious aerosols substantially. In a study of aerosols emitted during voluntary coughing and coughing due to sputum induction, Fennelly found that one patient coughing as a result of sputum induction generated approximately 600 colony forming units (cfus) of multi-drug resistant TB bacteria during the 10-minute test (Fennelly, 2004).

N95 respirators are required to provide a protection factor of 10 to the user, when properly fitted and used. Several recent studies (see, for example, Lee, 2008) have indicated that, because of the size of test aerosol used and the method of filtration, that some of these respirators may provide somewhat less protection, with a 95th percentile protection factor around 8. But even at a factor of 10, it is clear that the potential of infection to workers exposed to high hazard procedures may considerably exceed the protection factor of an N95 respirator. Surgical masks provide virtually no protection against respirable aerosols.

The Board does acknowledge that although newer PAPR designs reduce the noise and weight of PAPRs intended for use in health care settings, there may be situations where employees cannot use PAPRs. Therefore, the proposed standard states that PAPR use is not required where that use would interfere in the successful performance of the task or tasks. This permits the employer and employees to make the final determination as to whether a PAPR can be used.

This notice also includes a proposed modification to the PAPR requirement. This modification would permit the use of other respirators (such as N95s) by employees during high hazard procedures, where the patient is placed in a booth or other ventilated enclosure and the employee remains outside of the enclosure. This would apply to booths or hoods used for sputum induction or administration of aerosolized medications.

Finally, it is up to the employer to determine which procedures are high hazard. For example the use of closed circuit devices, or devices with filtered output, may reduce the hazard associated with some procedures and therefore may reduce the level of respiratory protection that is needed.

Comment #AF2: CACC believes that the requirement to notify other employers regarding an exposure incident should be modified to reflect the specific incubation periods and other disease characteristics that each disease would have rather than the 24 hour period required for all incidents.

Response: See response to comment #RR22.

Comment #AF3: Footnote number 1 to Appendix A requires airborne precautions to include droplet precautions. We are not aware of any reference including such a requirement, as the mechanisms for transmission differ between airborne and droplet transmitted diseases.

Response: See response to comment #RR23.

Lawrence Gibbs, Associate Vice Provost, Environmental Health and Safety, Stanford University, by letter dated August 13, 2008.

Comment #LG1: Mr. Gibbs commented that the laboratory section should exempt biomedical research laboratories which operate under the guidelines of the National Institutes for Health (NIH), and conform to the recommendations in the BMBL. The NIH further requires institutions receiving federal grants and doing research on recombinant DNA to develop a biosafety committee that approves research protocols, conduct inspections and assure adequate training of laboratory personnel, and perform other functions necessary to assure a safe environment. Since the monetary sanctions that would follow from a failure to implement these requirements are far

greater than Cal/OSHA penalties, such institutions already comply with these requirements and complying with the proposed standard would involve a duplicative effort that would be costly and time consuming. The proposed standard also applies a more conservative general risk characterization than is found in standard practice that would require more costly control measures that are not necessary.

Response: The Board notes that the Division and participants in the advisory process considered the recommendations of the BMBL, and in fact incorporated this document by reference. The intent of subsection (f) is to require employers to perform a risk assessment consistent with the BMBL and to implement control measures and a biosafety plan based on this risk assessment.

The commenter's belief that the proposed standard applies a more conservative general risk characterization may have come from an ambiguous introductory statement to Appendix D, which lists the pathogens for which risk assessments must be performed. This introductory statement has been changed, to reflect that inclusion on this list does not mandate biosafety level 3 (BSL-3) precautions. Rather, that determination is to be based on a risk assessment that includes both the pathogen and the processes in which the materials are used. Also, a new subsection (f)(2) has been added to require that a risk assessment, in accordance with BMBL, be conducted. Similarly the requirement to implement engineering and work practice controls has been modified (renumbered subsection (f)(3)) to reflect that the engineering and work practice controls should be based on this risk assessment.

In regards to Mr. Gibbs' statement that the NIH contracting system obviates the need for Cal/OSHA regulation, the Board is aware that Cal/OSHA penalties may not be a significant financial disincentive to violations. However, Cal/OSHA regulations are necessary to ensure that employers, employees and other interested parties are aware of these requirements. The California Labor Code provides a mechanism by which employees can seek to get hazardous conditions in their work place corrected in a timely manner, and the responsibility of Cal/OSHA to protect employees cannot be delegated to a contract between the employer and a third party. Further, periodic contract audits do not serve the same function. In the Division's experience enforcing other regulations in laboratory environments, the existence of a contractual relationship with NIH or other federal agencies does not always ensure compliance with occupational safety and health standards.

The Board understands that as originally noticed, the proposal raised some concerns among researchers that there would be a substantial expansion of required control measures beyond those generally recognized. The modifications proposed should clarify that the standard would require risk assessments and control measures that comply with BMBL and NIH guidelines. The Board believes therefore, that this proposal will not create substantial additional costs and will not adversely impact on research in California. The Board also notes that the financial and human costs of laboratory acquired infections can be devastating, and may lead to the termination of the research grant or project.

Comment #LG2: The proposed standard imposes a few more stringent requirements that are unnecessary that would entail extra time and costs, exemplified by the requirement to verify that biological materials marked as non-pathogenic which are received by the laboratory from an outside source are indeed non-pathogenic.

Response: Several recent incidents illustrate the need for the requirement to verify the safety of a received biological material represented as containing an attenuated or non-pathogenic strain. For example, in 2004 researchers at Children's Hospital Oakland Research Institute received a suspension from a contractor that was represented as containing non-viable anthrax, which was injected into mice. The mice unexpectedly died, as did a subsequent group of mice. When the incident was investigated, the suspension was found to contain viable anthrax. The Morbidity and Mortality Weekly Report (MMWR) editorial comment stated, "Inactivated suspensions of *B. anthracis* should be cultured both at the preparing laboratory before shipment and at the research laboratory several days before use to ensure sterility." (Lucas, 2005). Similarly, samples containing the 1957 pandemic H2N2 influenza strain were mistakenly sent by a CDC contractor to laboratories in 18 countries. It is common practice in laboratories to handle incoming samples represented as being an attenuated or non-pathogenic strain at BSL-2, until the nature of the sample has been verified. In addition, most establishments dealing with non-pathogenic strains have procedures for periodically validating that condition. For these reasons, the Board believes that a change to the proposed subsection is unnecessary.

Larry Wong, University of California Safety Manager, University of California Environmental Health and Safety Office of Risk Services, by letter dated August 21, 2008.

Comment #LW1: Proposed subsection (f) does not seem to allow a laboratory employer to assess the risks that are involved with the specific organism and type of task that is being utilized and determine the appropriate types of exposure controls that should be applied to that procedure. It is important for research facilities to be able to make an assessment of appropriate controls in accordance with the BMBL guidelines. Imposing the use of BSL3 controls for all the organisms listed in Appendix D would be unnecessary and would impose prohibitive costs on research grants and institutions.

Response: Subsection (f) and Appendix D as originally proposed were interpreted by a number of individuals as requiring BSL-3 control measures for all pathogens listed as ATP-L. However, this was not the intent of the proposed subsection, which was to require the biosafety officer to perform a risk assessment in accordance with the BMBL and establish appropriate control measures in the context of a biosafety plan. To ensure that this subsection is interpreted as intended, the introductory sentence to Appendix D is proposed to be modified to read: "This appendix contains a list of agents that, when reasonably anticipated to be present, require a laboratory to comply with Section 5199 for laboratory operations, by performing a risk assessment and establishing a biosafety plan that includes appropriate control measures as identified in the standard."

Also, a new subsection (f)(2) specifically referencing a BMBL risk assessment has been added: "The biological safety officer shall perform a risk assessment in accordance with the methodology included in Section II of the BMBL for each agent and procedure involving the handling of ATPs-L and record the findings of the assessment in the Biosafety Plan."

Finally, an additional phrase referencing the risk assessment in (f)(2) has been added to renumbered subsection (f)(3) regarding engineering and work practice controls.

The Board believes that this should remove any ambiguity and clearly direct employers as to the requirements of the subsection.

Comment #LW2: Regarding subsection (e)(1)(B) it will be difficult for an employer to show compliance with the implementation of source control measures if patients do not cooperate.

Response: This subsection does not require an employer to assure that a patient utilizes the source control measures that have been provided, but does require the employer to have made the measures available and to have ways to inform the patient of the need to make use of them. The effectiveness of these measures should be assessed as part of the annual review of the program.

Comment #LW3: Regarding subsection (c)(7)(J), the employee training requirement to have a trainer available to answer questions during every training session is impractical when the training must be given for multiple shifts which cover a 24 hour workday and all seven days of the week. Live trainers are not available for all these shifts. Computerized training allows more flexible training scheduling and can be augmented by having questions submitted and answered by a knowledgeable trainer in a reasonable time.

Response: Modified language is proposed to address this concern, and permit training methods other than in-person traditional training sessions. This would require answers to questions be provided within 24 hours, if a knowledgeable training is not present during the training session. See response to comment RR#9 for further discussion.

Comment #LW4: In subsection (g)(3)(B), the language should be changed to permit the use of PAPRs or equivalent protection,” to allow the use of other respirators.

Response: The language of this subsection has been changed to permit the use of a respirator providing equivalent protection.

Comment #LW5: In regards to subsection (d)(2)(D), the Exposure Control Plan should not be required to include a list of all tasks and assignments that require personal or respiratory protection because it will be very difficult to frequently update the information about which specific patients or rooms will require the use of protective equipment. It is better to have rooms posted with signs that designate for the employees which types of protection will be needed to work in a specific room.

Response: See response to comment #RR10.

Comment #LW6: Regarding subsection (d)(2)(N), the ECP should not be required to include a procedure for ensuring that there is an adequate supply of PPE and other equipment during emergency and surge situations. Under surge conditions, employers may not have access to supplies through the normal channels, or through prearranged vendor contracts and cannot ensure that the supplies will be accessible to them.

Response: The requirements for surge have been relocated to subsection (d)(2)(Q), and contain a reference to the local and regional emergency plan. For further discussion, see response to comment #RR11.

Comment #LW7: Regarding subsection (e)(3), the requirement to notify contractors who may have exposure to aerosol transmissible pathogens is phrased too loosely, so that it could be construed to include any contractor in the facility. The requirement should be applied only to contractors who are expected to enter rooms under airborne or droplet precautions or perform work on equipment that can generate aerosolized ATPs.

Response: A modification is proposed to change the wording of this subsection to require notification of contractors whose employees may be “reasonably anticipated to have occupational exposure,” to infectious disease hazards. It is up to the Plan administrator to determine which tasks would involve occupational exposure.

Comment #LW8: Regarding subsection (c)(3), the requirement to transfer an AirID patient to an airborne infection isolation room within the facility within a five hour limit is too restrictive because many facilities do not have many extra AII rooms that could accommodate periodic fluctuations in patients who would require the transfer. The exceptions that are provided for transfers to another facility should be available for the internal situation as well.

Response: Subsection (c)(3) refers to transfers by referring employers to hospitals and other facilities that provide services to airborne infectious disease cases. The issue of a five-hour time limit was discussed extensively in the advisory meetings. It was on the basis of these discussions that the exceptions provided both in subsection (c)(3), and in subsection (e)(5)(B) were developed. It is important that transfers of infectious AirID cases be accomplished in a timely manner, as referring employers are not likely to have airborne infection isolation rooms, and may not have respiratory protection programs. A longer timeframe is provided for persons who initially present at the referring employer after 3:30 p.m. and if there is no facility available to transfer the person to. This subsection also refers to additional exceptions in subsection (e)(5)(B).

Subsection (e)(5)(B)1 addresses transfers within the facility. Modified language is proposed to require that when in-facility transfers are not performed within five hours, then a between facility transfer be provided. That would then bring into play all of the exceptions that apply to those transfers, which are included in (e)(5)(B)2. With the several exceptions included in the standard, the Board believes that a five-hour limit is reasonable, and is necessary to protect the health of employees.

Comment #LW9: Subsection (e)(5)(D)4 does not identify the type of filters that are included in the requirement. The subsection should also delete the phrase that requires corrections to be made “in a reasonable amount of time” to be consistent with the CDC guideline language which does not contain that phrase.

Response: A modification is proposed to insert the term “exhaust or recirculation” before “filter” in order to identify filters to which this requirement applies. The exhaust or recirculation side filters are directly involved in capturing infectious particles prior to release or recirculation of the air.

The maintenance of effective airborne infection isolation rooms is critical to controlling employee exposures to airborne infectious pathogens. If problems are not corrected in a reasonable period of time, then infectious patients may not be able to be transferred to an AIIR,

which increases the potential for employees to contract disease. The language that problems be corrected in a reasonable period of time is performance language, intended to ensure the availability of properly functioning AIIR. The Board does not agree that the language proposed by the commenter provides a better framework for addressing maintenance of engineering controls, such as HEPA filters, since it does not give as much notice to employers and employees regarding requirements for maintenance of these controls.

Comment #LW10: Regarding subsection (h)(5)(D), ten days is too short a time limit for providing vaccine to an employee who originally declined it. Also, this subsection should require that the employee make a written request for the vaccine.

Response: In order to clarify how vaccine will be provided to an employee who originally declined a vaccine, and then decided to accept the vaccine, a phrase has been added to this subsection to reference the provision of vaccine to subsection (h)(5)(A). The requirement to provide the vaccine within ten days is conditioned on the availability of the vaccine, as indicated by the exception to subsection (h)(5). Also, language has been added to require the provision of the vaccine after receipt of a written request. In reviewing the experience of enforcing a similar ten-day requirement for provision of hepatitis B vaccine under Section 5193, the Division has found that this requirement is generally practicable.

Comment #LW11: In regards to subsection (h)(6), the time limits of 24 hours for analyzing the exposure scenario of an exposure incident and the 48 hours allowed to make the notifications may not allow the employer enough time in practice. Further, the term “significant exposures” should be defined.

Response: In regards to the timeframes in subsection (h)(6), a modification is proposed to provide more flexibility for notifications, based upon the disease, and providing an outer limit to the time frames of 72 and 96 hours, respectively. See comment #RR22 for further discussion of this requirement.

Significant exposure is defined in subsection (b) to mean “an exposure to a source of ATPs or ATPs-L in which the circumstances of the exposure make the transmission of a disease sufficiently likely that the employee requires further evaluation by a PLHCP.” This performance definition is to be applied by an individual who (subsection (h)(6)(C)1) is “knowledgeable in the mechanisms of exposure to ATPs or ATPs-L.” The Board believes that this is an appropriate approach to addressing exposure incidents.

Comment #LW12: The Board should re-examine the content of the proposed Standard and condense the laboratory relevant sections into a separate appendix that connects the desired outcome of a safe and healthy laboratory workplace concomitantly with the available resource of the NIH, CDC as well as OSHA. This was done successfully with Bloodborne Pathogens.

Response: The proposal includes a separate section on laboratories (subsection (f)) and Appendix D, which provides a list of pathogens. Risk assessment is incorporated into subsection (f), as are the BMBL guidelines. This is similar to the structure of Section 5193, which addresses certain laboratory operations under subsection (e), while also applying certain requirements of the general standard to laboratory operations.

David Campbell, Ph.D., Chair, Institutional Biosafety Committee and Roberto Peccei, Ph.D., Vice-Chancellor of Research, University of California, Los Angeles, by electronic mail dated August 20, 2008.

Comment #DC1: UCLA strongly supports the comments submitted by Stanford University in regards to laboratory operations. The commenters believe that this standard would have a negative impact on the research community in California. The proposal is redundant with existing NIH requirements, and does not provide delineated risk assessment for each regulated agent and its use in the laboratory. Requirements are elevated to higher containment and practices without appropriate cause. For example, inclusion of adenovirus and retroviruses as pathogens requiring aerosol control or Biosafety Level 3, disregards that there are readily available avirulent or attenuated strains of these agents. These agents can be used for human gene therapy studies, and assigning aerosol control or BSL3 to such agents will impact studies and hinder research.

Response: Changes have been made to subsection (f) and Appendix D to clarify that inclusion of pathogens on the list in Appendix D triggers a risk assessment, and does not necessarily require BSL3 practices or containment. See response to comments #LW1, #LG1, and #LG2 for further discussion.

Donna Gerber, California Nurses Association and National Nurses Organizing Committee, by letter dated August 15, 2008, and Deanna Furman, Legislative and Community Advocate for the California Nurses Association (CNA), oral comments received at the August 21, 2008, Public Hearing.

Comment #DG1: The California Nurses Association supports strong regulations to protect health care workers and many areas of strength are evident in this regulatory package. There are numerous and increasing threats from emerging diseases and multiple drug resistant organisms that impact health care workers directly. The inclusion of the term novel and unknown pathogens is very important to protect the health care workforce from the currently unknown and as yet unidentified pathogens.

Response: The Board thanks the Ms. Gerber, Ms. Furman, and the CNA and NNOC for their comments.

Comment #DG2: In regards to Section 5144, it is important that the “fit test” for the respiratory protection equipment not be used under any circumstances to discriminate in the workplace or in the health care coverage the health care worker holds.

Response: Fit testing required by this standard (and Section 5144) is designed to ensure that the respirator fits the health care worker, and should not relate to the health status of the employee. Medical evaluations and fit tests are currently required for all employees using respirators, including health care workers, under Section 5144, and issues relating to protecting employees from discrimination in the workplace would not be affected by this proposal. As required by Section 5144, an employer is responsible to offer more than one respirator for use in the workplace, so that employees may be provided with a good fitting respirator.

Comment #DG3: The regulation should retain annual fit testing to assure compliance and worker protection, rather than biannual fit testing.

Response: The proposal includes an exception permitting biennial fit-testing for employees who do not perform high hazard procedures, which will sunset in 2014. The intent of this exception is to maximize the number of health care workers who are prepared to use respirators, by providing them with annual training and initial and periodic fit-testing. The modified proposal includes an additional requirement that employees of employers who only provide biennial fit-tests be annually surveyed to determine if they have had facial or weight changes that may effect respirator fit, or if they want an additional fit-test. The Board believes that this standard will protect health care workers against aerosol transmissible diseases while ensuring that health care organizations do not unduly restrict respirator use in order to conserve resources. Please see the response to comment #BK18 for additional response on this issue.

Comment #DG4: The commenter strongly supports the recommendation that employees performing high hazard procedures on suspected or confirmed airborne infectious disease cases be provided with the high level of protection provided by powered air purifying respirators (PAPR). All registered nurses, and other health care workers, should be trained in their use. Droplet precaution should be viewed as aerosol transmissible disease/pathogen as a practical matter.

Response: Aerosol generating procedures (high hazard procedures) may generate aerosol concentrations that are ten times or more higher than other patient care activities (Fennelly, 2004). For this reason, the proposal specifies a higher level of protection for these activities. It is up to the employer, with the input and review of employees, to determine which employees need to be trained for PAPR use, based on current assignment and foreseeable surge situations. Diseases requiring droplet precautions are included within the scope of the standard. However, based on current public health recommendations, they do not require airborne infection isolation.

Comment #DG5: This regulation should provide protection for exposure to animal diseases, such as *Mycobacterium bovis*, which can infect humans.

Response: The Board agrees that all human *Mycobacterium tuberculosis* complex infections should be included in this standard, and the proposal has been changed to clarify that the term *M. tuberculosis* means the complex, which includes *M. bovis*, *M. africanum*, and *M. microti*. Avian influenza is also specifically included in Appendix A, as is SARS and monkey pox. If new aerosol transmissible zoonotic diseases emerge, they will be considered novel and unknown pathogens, and therefore addressed by the requirements of this standard. In regards to laboratories, Appendix D includes a number of zoonotic pathogens.

Comment #DG6: Clear, accurate, timely, and focused communication is important to preventing and ameliorating workplace problems, and is an important training element. All workforce sectors of health facilities should be held accountable for communication to protect employees, patients, families and their communities.

Response: The Board agrees that communication is necessary to protect employees from disease, and notes that there are a number of provisions in this proposal addressing communication.

Comment #DG7: The commenter is concerned that most of the employers within the scope of the standard would be considered referring employers, to whom only “minimal” requirements would apply. These employers do not provide services beyond first aid and initial treatment to patients requiring airborne infection isolation, as AirID suspect or confirmed cases. The commenter believes that the underlying assumptions for distinguishing between referring employers and other employers are faulty. “Individuals who have airborne transmissible disease (ATD) may not know they have it, or may not remember or report accurately their symptoms, including the severity and duration.” The commenter states, “The very high rate of uninsured and underinsured residents of California (many of whom are healthcare workers) means that a portion of the population who may seek health care in medical offices and clinics, homeless shelters, drug treatment programs, hospices, long-term care facilities, or are sent to jails, are, in fact infectious with an airborne transmissible disease.”

The commenter further states that health care workers in referring employer environments will be exposed to airborne transmissible diseases that require both droplet precautions and airborne infection isolation. An additional problem is the “disturbingly low” level of personal health literacy among the general public.

Response: The standard distinguishes between referring employers and employers who house, treat or otherwise manage AirID cases and suspected cases in order to ensure that patients who are infectious with diseases requiring airborne infection isolation are, in fact, appropriately isolated. Homeless shelters, drug treatment programs, and most primary care practices do not have airborne infection isolation rooms. Homeless shelters and drug treatment programs, and some correctional facilities and police operations do not have personnel who are trained in medically managing ATD cases. Therefore, the primary method of protecting workers in referring employer environments is early case recognition and prompt placement of those people requiring airborne infection isolation in an appropriate facility. For referring employers who do not have health care providers, the emphasis is on referring people who manifest certain easily recognized symptoms, as described in Appendix F, to health care providers.

In addition, source control measures such as separating the patient and providing a mask or tissues and hand hygiene materials, vaccination of health care workers, annual TB assessment, employee training, and procedures for exposure incidents will further reduce the risk to those employees.

Health care operations, such as home health care, which may be providing services to persons with infectious TB or other diseases requiring airborne infection isolation and are managed in a home or community setting, would not be considered referring employers.

Through ten advisory meetings, public health guidelines, research and the direct experience of health care workers and organizations were reviewed and discussed, in order to develop a proposal that could be implemented and provide protections that would reduce the risks to health care workers and other workers in high risk environments. Everyone who interacts with the public, students, customers, or other people runs the risk of exposure to infectious diseases. However, experience has shown that people who perform high hazard procedures, or who have prolonged or intense contact with infectious people are at higher risk.

The intent of creating the referring employer category is to require employers to have infection control procedures that are appropriate for the specific risks and exposures in their environments. These procedures may be very different in homeless shelters, where there may not be medical providers on-site, than they are in skilled nursing facilities or primary care offices and clinics.

Comment #DG8: The commenter believes that exempting dental offices and outpatient medical specialty offices from the standard if they screen patients for ATDs, refer those patients, and do not perform aerosol-generating procedures on those patients, is based on the faulty assumptions that underlie the referring employer category.

Response: The proposal is designed to address those workplaces at which employees are at higher risk than employees in other public contact operations. Aerosol generating dental procedures may transmit aerosol transmissible diseases, and dentists who perform these procedures on persons who have an ATD are covered by this standard. However, current dental practice guidelines advise dentists to screen patients for ATDs before performing procedures on them. The Board believes there is a necessity to ensure that employees are trained in screening procedures and that these procedures are implemented. Therefore, the proposal has been modified to require written screening procedures and training of employees in these procedures. See response to comments #BK2 and #BK3 for further discussion of these provisions.

Comment #DG9: The commenter is concerned regarding how worker protections are being integrated into the All Hazards Disaster Response of health care facilities, communities, regional and public health departments. How would it address alternate care sites, which will be staffed by health care providers and non-health care providers, and how would Appendix F apply? Also, it is essential that appropriate supplies be on hand for immediate use during a public health surge.

Response: Subsection (d)(2)(F) and (d)(2)(M) as first noticed by the Board contained requirements regarding surge planning. The revised proposal relocates these requirements to subsection (d)(2)(Q) which also references local and regional emergency plans. Subsection (i)(4)(L) also requires employees to be trained in the employer's surge plan.

Appendix F is meant to apply to situations in which health care providers are not available to perform screening.

Comment #DG10: The commenter states that in discussing costs and savings, the costs avoided from workers compensation claims, lost work time, and productivity losses to the employer, as well as employers of the employee's family, as well as the harm due to significant illnesses, disabilities and premature death, should be considered as potential savings due to the proposed standard.

Response: The Board has included projected savings related to vaccination and certain other provisions in the cost estimates of this proposal, and thanks the commenter for calling attention to the significant harm, as well as costs that result when an employee contracts an ATD.

Vickie L. Wells, CIH, CSP, Director, Occupational Safety and Health, City and County of San Francisco, by letter dated August 21, 2008, and oral comments received at the August 21, 2008, Public Hearing.

Comment #VW1: Many facilities that do not provide health care services do not have rooms or areas equipped with a separate ventilation system where a symptomatic individual can stay while awaiting transportation. It is not clear who can establish what is feasible for the establishment to do to provide such an area.

Response: The Board agrees that there will be facilities that are not equipped to provide areas with separate ventilation. The issue of feasibility has to be considered in light of the reasonableness requirements of Labor Code sections 6401 and 6403. A determination of feasibility requires a good faith effort on the part of employers to assess their capabilities and the level of risk. This determination may differ between employers, even in the same sector. For example, some homeless shelters are essentially a large area where cots or other temporary beds are placed. The most that can be feasibly done in that situation may be to place a possible ATD case in an area separated by as much distance as possible from where others are located. Other shelters may have a side room where a person can be placed. Similarly, some clinics may have an examination room or other room with a separate ventilation system, while others may not. A facility that frequently is in the position of temporarily housing individuals requiring referrals may need to put more resources into developing control measures than one that does not. Ultimately, the burden in this standard will lie on the Division to establish that a feasible method was not used.

Comment #VW2: The requirement in subsection (d)(2)(E) to list specific engineering controls and other specific protective measures for each task where occupational exposure may occur is impossible because there are so many tasks in that category. Also, the protective measures to be taken would depend on the specific organism of concern.

Response: The purpose of this subsection is to address how facilities, services or operations will implement the requirements of this standard. The purpose of listing specific control measures is so that employees and employers can be aware of how ATD risks will be controlled in a specific operation. While it is true that some control measures are based on the specific pathogen, control measures must often be implemented before the actual disease agent has been identified.

The Board agrees with the comment to the extent that a requirement to list control measures by task or group of tasks may appear to require more detail than is necessary or practicable in a written plan. Therefore, modified language is proposed to remove the words “type or group of tasks,” leaving the requirement to apply to operations or work areas. The rest of this subsection explains that the Plan must include the applicable engineering controls and work practice controls, cleaning and decontamination procedures and personal protective equipment and respiratory protection, for an operation or work area. In developing the Plan, the employer should address operations or work areas, in a manner appropriate to the facility. For example, a hospital may choose to address all airborne infection isolation rooms in the facility as one type of operation, and may in addition state that when the patient in the room is a suspect or confirmed SARS case, that additional personal protective equipment must be used. The Board believes that with the modifications proposed, employers will be able to efficiently structure the Plan to provide the necessary guidance to supervisors and employees.

Comment #VW3: In regards to subsection (e)(5)(B)2.d, it is not within the current scope of duties for local health officers to recommend measures to use when an individual cannot be

transferred to an airborne isolation room within 24 hours. This is not an appropriate task for a local health officer and this responsibility should not be assigned to the local health officer [LHO].

Response: Representatives of the California Conference of Local Health Officers were active during the advisory process. Division staff specifically queried the CCLHO on this issue in 2006, and again in response to your comment. These representatives indicated that the language in the standard in regards to the LHO is within the scope of their authority and duties (Iton). Further, this subsection does not assign to the LHO a responsibility to make recommendations, it only requires the facility to follow any recommendations made by the LHO to prevent further spread of disease.

Comment #VW4: Subsection (e)(5)(D)2 should require conformance with the 2005 CDC Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Healthcare settings and adopt them by reference.

Response: The Board notes that this document is incorporated by reference in the definitions listing in subsection (b) of the proposed standard, and reference is made to this document in subsection (e)(1)(A). The purpose of specifically stating the ventilation requirements in this subsection, which are consistent with the referenced document, is to provide clear notice to employers and employees of these requirements.

Comment #VW5: Subsection (e)(5)(D)3 should be revised to state: "Negative pressure shall be demonstrated by smoke tubes, other visual checks or equally effective methods daily while a room or area is in use for AII."

Response: The term "visual checks" has been used in CDC publications, however, the only method other than smoke trails that is mentioned is the use of strips of paper or other lightweight material that are attached near a ventilation intake or exhaust in a room and intended to move with the air movement into or out of the opening as a qualitative indication that the system is operating. These would not necessarily demonstrate negative pressure. However, the existing language allows for the use of equally effective means to smoke tubes, which would permit strips or other visual indications if they are effective. Consequently, the Board declines to make the recommended change.

Comment #VW6: In regards to subsection (e)(5)(D)9, the method for calculating 99.9% removal efficiency in the Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-care Settings is not straightforward. Cal/OSHA should include the calculation method in the standard or provide alternative methods. Also, evidence supporting the 99.9% standard should be provided before including this requirement in the standard.

Response: The requirement for requiring respirator use until the room has been sufficiently ventilated to provide a removal efficiency of 99.9% is included in the 2005 CDC Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Healthcare settings, and was determined by the CDC to be necessary to protect employees against contracting tuberculosis. The document provides the method of calculating removal efficiency in Table 1. This table shows how many minutes it takes to achieve 99% and 99.9% removal of aerosols at specific rates of air changes per hour, which means how many times the total volume of air for a given

room can be removed (and replaced) by the ventilation system installed in that room in the period of an hour. The Board agrees that the method of calculating air changes per hour based on volumetric air flow, which has been incorporated into CDC TB guidelines through many revisions, is not a precise calculation of removal efficiency, and an accurate determination of removal efficiency would require a much more complicated method of measurement. However, the Board believes that the method included in the CDC guideline is the most practicable approach to determining when respirator use can be discontinued. The phrase “Table 1” has been added to this subsection in order to clarify that this is the method to be used to calculate the time necessary for 99.9% removal.

Comment #VW7: Subsection (g)(4)(B) seems to include any patient with a droplet transmissible infection, or any of the infections listed in Appendix A. This should apply only to pathogens requiring airborne infection isolation. There is no scientific evidence of airborne transmission of diseases requiring only droplet precautions, such as pertussis, that would warrant this level of protection. Also, is a PAPR required for nebulizer treatment of a patient with an extrapulmonary draining lesion?

Response: Subsection (g)(4)(B) only addresses provision of services for airborne infectious disease (AirID) cases and suspected cases. Further, a PAPR would only be required for high hazard procedures on an AirID case or suspected case (see subsection (g)(3)(B)). The proposal would not require a PAPR, or any respirator, for pertussis, although the employer may choose to require one. In regards to extrapulmonary tuberculosis, Appendix A of the Guideline for Infection Control in Healthcare Settings lists extrapulmonary tuberculosis, draining lesion as requiring airborne precautions.

Extrapulmonary, (draining lesion)	A,C	Discontinue precautions only when patient is improving clinically, and drainage has ceased or there are three consecutive negative cultures of continued drainage ^{1025, 1026} . Examine for evidence of active pulmonary tuberculosis
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This recommendation was discussed with the office of the CDPH Tuberculosis Control Branch. They indicated that there are very few cases (about one per year) of extrapulmonary TB with draining lesions that did not also have pulmonary TB. In addition to irrigation of extrapulmonary TB lesions, the recommendation for airborne infection isolation is based on the possibility that there is undetected pulmonary TB, as indicated in the comment section in the above box. In addition, the standard provides the employer with sufficient flexibility to identify whether administration of aerosolized medications to a patient that does not have pulmonary TB (or other AirID), is a high hazard procedure.

Comment #VW8: Appendix A should be clarified to indicate that extrapulmonary tuberculosis is on the airborne isolation list because of risks during irrigation procedures because currently only standard precautions are recommended by HICPAC/CDC for this condition. Are there any other diseases or conditions, such as a draining lesion in which potentially aerosolizing procedures may take place where airborne precautions would be recommended?

Response: Please see response to comment #VW7 regarding extrapulmonary TB. In regards to other diseases or conditions that may require airborne isolation for aerosol generating

procedures, such as procedures involving multi-drug resistant organisms, employers should make that determination based on current public health guidelines.

Comment #VW9: Regarding Appendix A, to what specifically does “serious invasive disease” listed in droplet precautions refer?

Response: A formatting error in the Appendix separated this line from the line it referred to, which was Group A streptococcus. The reformatting of Appendix A in the modified draft, will list it under “Streptococcal disease (group A streptococcus).”

Comment #VW10: In Appendix A, for Viral hemorrhagic fevers, the following statement should be added, “Consider airborne precautions during aerosolizing procedures.”

Response: The Board agrees that this would be an appropriate statement to add to the text and proposes this addition as a modification to the appendix.

Comment #VW11: Appendix C should be amended to allow equivalent declination forms.

Response: Subsection (h)(10) requires employers to ensure that the declination statement contained in Appendix C2 be signed by employees who do not accept influenza vaccine. It does not require the use of a specific form. An exception to subsection (h)(10) permits the use of other influenza vaccination vaccine declination forms that are acceptable to the CDPH for licensed facilities.

Julie R. Jackson, CIH, CSP, Corporate Biosafety and Chemical Hygiene Officer, Corporate Quality, Environment, Health and Safety, Amgen Inc., by letter dated August 21, 2008.

Comment #JJ1: In regards to subsection (a)(2) it is unclear as to whether a walk-in onsite health clinic is exempted under this standard.

Response: The issue of whether a walk-in onsite health clinic is considered an outpatient medical specialty practice that does not diagnose or treat ATDs must be determined by each clinic. To come under the exemption, the walk-in clinic must also include screening procedures in the Injury and Illness Prevention Program. Other walk-in clinics would likely be referring employers. A definition has been added to subsection (b) to clarify what is meant by a medical specialty practice. The term outpatient facility refers to facilities in which patients are not housed.

Comment #JJ2: In regards to subsection (a)(3)(A), the statement that to be a referring employer, the facility, service or operation “must do or not do each of the following” is confusing.

Response: This subsection has been reworded for clarity.

Comment #JJ3: Regarding subsection (a)(1)(I), this section as worded could be read to broadly include a variety of building maintenance operations.

Response: The language of this subsection has been modified to indicate that it refers to those maintenance, renovation, service or repair operations that involve areas or equipment reasonably

anticipated to be contaminated with ATPs or ATPs-L associated with AIIRs or areas in which AirID cases and suspected cases are housed, etc. It is meant to apply to operations in which an employee may be exposed indirectly to pathogens from a case or suspected case, or a laboratory material.

Comment #JJ4: Regarding subsection (b) the definition for AIIR should exclude the areas covered under the laboratory section.

Response: Subsection (a)(3)(B) identifies those subsections that apply to laboratories in which employees do not have direct contact with cases or suspected cases of ATDs or infected cadavers. Those subsections do not include subsection (e) which contains requirements for AIIR. Requirements for AIIR appropriately apply to laboratory operations in which there is direct patient contact, because the purpose of this engineering control is to prevent exposure to employees outside of the room or area.

Comment #JJ5: Subsection (f) does not but should support the risk based approach that is described in CDC's BMBL even though it is incorporated by reference. Also, laboratory facilities that do not receive government funding and are thus not obligated to maintain a Biosafety Committee nevertheless have an industry standard to perform a review of research with recombinant DNA and experiments with infectious agents prior to the initiation of experiments including a risk assessment with the principal investigator. Approval for the project may be granted after the risk assessment is performed.

Response: The Board agrees that risk assessment should be clearly included in subsection (f), and modifications have been made to the proposed standard to this effect. See response to comment #LW1 for more discussion on this issue.

Comment #JJ6: Appendix D of the proposed standard seems to impose more conservative characterizations to infectious agents that are commonly used throughout the research industry. Some of the organisms lack qualifiers, and others are more likely to be transmitted through percutaneous injuries. Some adenoviruses are used as a basis for gene therapy, and there should be a qualifier explaining when they are included. Appendix D does not account for the factors that would make lentiviruses or retroviruses less pathogenic such as rendering the virus replication deficient before use, thus preventing reproduction in the host as a disease.

Response: Appendix D, as originally noticed was compiled by participants from laboratories involved in the advisory process. It was derived from BMBL entries pertaining to pathogens that may require aerosol controls under some circumstances, and from pathogens identified by the Guideline for Isolation Precautions. Listing in Appendix D was only intended to trigger a requirement for risk assessment, not to specify BSL-3 precautions. However, the number of comments received on this issue have illustrated the need to clarify this language, and the language in subsection (f). Therefore, the introductory language in Appendix D has been modified to indicate that listing in Appendix D requires the biosafety officer to perform a risk assessment. In addition, a new subsection (f)(2) is proposed to specifically address risk assessment, and language is added to requirements for engineering and work practice controls (relocated to subsection (f)(3)) that references those controls to the risk assessment. Further Appendix D now contains an annotation to adenovirus that states that it applies only in clinical samples and culture and materials derived from clinical samples. These provisions permit the

biosafety officer to determine the level of control measures necessary for modified virus strains. See responses to comments #LG1 and #LW1 for further discussion of this issue.

Comment #JJ7: Appendix A seems to exclude pathogens on the Droplet List from the requirements of the standard.

Response: The Board notes that Appendix A provides the list of aerosol transmissible diseases. Both diseases classified as requiring airborne infection isolation and diseases classified as droplet are covered by this standard. A modification is proposed to the introductory language of Appendix A to clarify that provisions of Section 5199 apply to both categories of diseases (airborne and droplet), but that airborne precautions only apply to those listed as “airborne.”

Comment #JJ8: The training requirements may be onerous and difficult to accomplish. The requirement to have a qualified instructor precludes the use of web based training. Secondly, it is onerous to individually identify staff annually who need to be trained. Thirdly, it is onerous to provide the epidemiology of each agent that may be present in laboratories.

Response: A number of comments were received regarding the need to address modes of training other than in-person sessions. For that reason, subsection (i) has been restructured to address how an opportunity for interactive questions will be provided if training is not provided in person by a knowledgeable trainer. For more details, please see comment #RR9 for further discussion.

The Board does not agree that it is difficult to identify staff who need training, and notes that there are many other annual training requirements such as respiratory protection and bloodborne pathogens. Annual training is particularly necessary because work practice controls are key to preventing exposure in a laboratory context. In regards to training on the “epidemiology” of each agent, there is no requirement in this proposal to that effect. Training is required to address a general explanation of ATDs including the signs and symptoms of ATDs that require further medical evaluation, and an explanation of the modes of transmission of ATPs or ATPs-L and applicable source control procedures.

Comment #JJ9: In regards to subsection (h)(5), vaccinations for laboratory employees, this may be a problem as it is not clearly stated that these vaccines are limited to commercially available vaccines.

Response: In order to clarify vaccine requirements, this subsection has been changed to refer vaccination requirements to the BMBL, which recommends commercially available vaccines.

Comment #JJ10: This standard duplicates some of the requirements of Section 3203, for example the biosafety plan duplicates requirements of Section 3203.

Response: The advisory process identified a need to more specifically address required control measures for aerosol transmissible diseases. The intent of a vertical standard such as this is to create a matrix of control measures. While it is true that Section 3203 requires a written safety and health program, it cannot be construed to require all of the specific elements that are necessary to building an effective biosafety plan or exposure control plan.

Comment #JJ11: There is no differentiation described for Biosafety Level 3 and aerosol droplet precautions. Consequently, it is unclear as to whether adenovirus may need to be manipulated at Biosafety Level 3. The wording of Appendix A implies that the standard is not applicable to the list of pathogens on the droplet precaution list.

Response: The precautions to be taken with any pathogen in a laboratory are based on the risk assessment performed by a biosafety officer, in accordance with the BMBL. The modified proposal contains a reworded introduction to the lists on Appendix A to clarify that the requirements of the proposed standard apply to all aerosol transmissible diseases, droplet and airborne, but that airborne infection isolation requirements only apply to diseases or pathogens classified as airborne.

Sean Barry, Campus Biological Safety Officer, Environmental Health and Safety Department, UC Davis, by oral comments at the August 21, 2008, Public Hearing.

Comment #SB1: Subsection (f) establishes a requirement that the University already meets. They are required to have an institutional biosafety committee to review all research, research labs, and research activities on all of the UC campuses, and that requirement has been in place with NIH since 1974. It was originally directed at recombinant DNA research in particular. The research involves microbes and pathogenic microbes and the committee is specifically charged with performing a risk assessment on every piece of research. The proposal as written does not allow space for risk assessment, and safety committees would feel that they were being second-guessed by the proposal.

Response: The Board notes that other comments received from laboratory operations made similar comments regarding the absence of a “risk-assessment” requirement. As explained in the response to #LW1, the Board proposes a modification to clarify this issue. Also the issue of potential redundancy of requirements is addressed in the response to comment #LG1.

Comment #SB2: Many institutions already have a committee review process for a safety assessment of proposed research. They have an institutional safety committee that evaluates the proposal and decides if an approval is appropriate or not. The researcher needs a use authorization from this committee in order to proceed with the experiment or process.

Response: Existing biosafety structures, such as biosafety committees, can be an important part of the employer’s biosafety plan, as required under this section. There is no contradiction between the guidelines to which the commenter refers, and requirements under this section. There is further discussion of this issue in the response to comment #LG1.

Comment #SB3: The list of pathogenic organisms in Appendix D does not seem to make allowance for the use of metaviral or genetically modified agents that are quite useful for all sorts of genetic investigations.

Response: Modifications are proposed to the introduction to Appendix D, and to subsection (f) to clarify the Board's intent that the employer perform a risk assessment based on recognized guidelines, which can take into account modifications of the agent. The specific listing of adenovirus has been modified to reflect that it only applies to clinical specimens and cultures and other materials derived from clinical specimens. Further discussion is included in the response to comments #LW1, #LG1 and #JJ6.

Donna Bennett, FNP, COHN-S, Employee Health Services, Lodi Memorial Hospital by electronic mail dated July 25, 2008.

Comment #DB1: Documented immunity by blood titers to the aerosol transmissible diseases should be included as an acceptable record in place of documentation of vaccination.

Response: Subsection (h)(5) would require employers to make the vaccine doses listed in Appendix E available to all susceptible health care workers. Susceptibility is to be determined in accordance with Epidemiology and Prevention of Vaccine-Preventable Diseases, published by the CDC. Titers are one method of determining immunity, however, depending on the disease, they may not always provide sufficient information. An employee who does not decline a vaccination will be provided with the vaccine by a PLHCP, who may determine that the employee is immune and does not need the vaccine. The standard, however, prohibits employers from requiring that employees participate in a serology screening as a condition of providing the vaccine. This is in order to prevent delay in providing a needed vaccine and to prevent employees from declining the vaccine because they do not wish to participate in a serology program for personal or religious reasons.

Comment #DB2: It is unclear why the annual fit testing requirement would be changed for six years to a biennial requirement and then changed back to annually. "It is not reasonable to fit test employees for a mask they will not be wearing. The N95s are disposable and therefore different every time they are used. If the employee is trained to do a fit check each time the mask is worn, they should not need refitting unless there is a change in facial structure or they are having problems. Annual fit testing is a monumental waste of man hours and creates unnecessary waste in landfills. I have 800 employees fit tested every year in addition to new hires. That is 800+ respirators that could have been used for a legitimate need to actually protect someone."

Response: Annual fit-testing is currently required by Section 5144. The Initial Statement of Reasons discussed the purpose of the exception, permitting a less frequent periodic fit-test interval until 2014. Periodic fit-testing is necessary because employees are not always aware of facial changes that influence respirator fit, and to reinforce the proposed use of respirators. For additional comment on respirator fit-testing please see comment #BK18.

Comment #DB3: The fit testing process is cumbersome and should be amended to reduce the amount of time it takes to perform. The test procedure should be altered to allow the tester to determine the employee's ability to taste/smell the test solution after the mask is tested, because in her experience most of the time the employee can detect the smell with one puff of the solution.

Response: The fit-test methods are required by Section 5144 and by the equivalent federal regulation 29 CFR 1910.134. They have been validated by extensive testing. The purpose of

determining the taste threshold of the employee prior to the test, is that it is used to determine how much of the test agent is applied to the atmosphere outside of the respirator during testing. This is used to ensure that the respirator provides a sufficient level of protection. It should be noted that in addition to the taste agents used for N95 qualitative fit-tests, Section 5144 and this proposal permit the use of two quantitative methods.

Victoria Becker, RN, by letter dated August 4, 2008.

Comment #VB1: The commenter states that she is a registered nurse in California. She believes, based on her experience as a nurse, that it is very important that the Board adopt the proposed regulation. Currently, there are a lot of voluntary guidelines, but, unlike bloodborne pathogens there is no regulation that specifies what is necessary to protect employees. When she was working as a home health nurse, she was assigned to visit a TB patient who had recently been discharged from the hospital. The initial information she was provided indicated that the patient had been hospitalized for two weeks, and was not infectious, and that she didn't need any protective measures. But when she asked for documentation of his discharge, it turned out he had not been hospitalized for two weeks, he had not had three consecutive cleared sputums, and he was considered infectious. She then had to argue with her supervisor to get fit-tested for a respirator, and when they had trouble finding a respirator that fit, her supervisor tried to get her to do the visit with a respirator that had not passed the fit test. When she called Cal/OSHA, they said the employer is required to provide a fit-test if they require respirator use, but that Cal/OSHA might have trouble establishing that a respirator is required in a home health situation. Therefore it is important that this proposal requires the use of respirators in home health care operations.

Response: The Board thanks Ms. Becker for her comments and agrees that home health care operations belong within the scope of this standard.

Comment #VB2: This section should apply to people who work in all home care operations, including in-home support services. People requiring personal care may be immune-compromised, and latent TB may become infectious. The people who provide personal care generally do not have the knowledge to determine whether a patient may be infectious. Therefore, this standard should apply to all home care operations, not just home health care.

Response: See response to comment #MC2.

Comment #VB3: The communications provisions, and provisions for medical follow-up are very important. Home health nurses are often sent out to visit patients without adequate information about who may be present in the home with infectious diseases. It is important that employers be required to tell nurses about the patient's status as part of the initial assignment. When nurses and other employees get exposed, they need to be provided with prompt and knowledgeable medical care.

Response: The Board thanks Ms. Becker for her support for these provisions.

William T. Fujioka, Chief Executive Officer, and Steven E. NyBlom, Manager, Risk Management Branch, County of Los Angeles, by electronic mail dated August 21, 2008.

Comment #WF1: The Initial Statement of Reasons (ISOR) does not include a cost/benefit explanation of the need for this regulation and does not accurately estimate the costs associated with implementing the various programs required by the regulation. The regulation would impose significant financial burden on local governments, in particular peace officer and firefighting agencies. For example, Section 5199 would require annual TB skin testing of all 60,000 peace officers in the state without any evidence of increasing TB rates among peace officers not assigned to correctional facilities.

Response: The Board disagrees with the statement that the ISOR does not adequately address the costs and benefits of the proposed regulation. The necessity for this regulation is discussed in general in the ISOR summary, and with great specificity the necessity and benefits are elaborated for more than 40 pages in the section of the ISOR titled *SPECIFIC PURPOSE AND FACTUAL BASIS OF PROPOSED ACTION*. Cost estimates begin on page 46 of the ISOR. Estimated costs for each proposed subsection of the regulation are discussed. Firefighters and peace officers would generally be considered employees of Referring Employers; costs for this type of employer are detailed from page 47 to page 49. The Board notes that many of the proposed requirements for jails and other correctional facilities are currently required by Titles 15 and 17 and therefore do not impose new costs. Tables in the ISOR illustrate that the cost for vaccinations is offset by savings from employees not having to take sick leave.

Finally, the comment that all of California's peace officers would have to be given the TB skin test is a misinterpretation of the regulation's requirements. The Board agrees that many peace officers are not occupationally exposed to aerosol transmitted diseases. "*Occupational exposure*" as defined in the definition section of the standard requires circumstances that elevate the risk of contracting any disease caused by ATPs or ATPs-L. Thus only some peace officers or firefighters would have to have the TB skin test: those who are reasonably anticipated to be exposed to a source of ATPs that is elevated above the exposure risk incurred by employees in public contact operations not included within the scope of the standard, such as retail clerks or public transit operators. Examples of peace officers who are likely to be included in the standard are those who work in correctional facilities or who transport or maintain in custody persons who are ATD cases or suspected cases. It is up to the employer to determine which officers have occupational exposure in the course of their duties.

Comment #WF2: The Standards Board needs to show that the targeted diseases are rising in incidence, while TB is in fact dropping in incidence.

Response: The Board disagrees that it is required to show an increase in TB or other targeted diseases in order to adopt a standard. The Board is required to adopt standards that are necessary to protect the health and safety of employees. Health care workers and other workers identified in this standard continue to have exposure to ATDs in the course of their work, and are additionally being prepared to deal with a potential outbreak of pandemic flu or other disease outbreak. The Initial Statement of Reasons contains the factual basis for this standard. Additional discussion is provided in response to comment #AF1.

Comment #WF3: Subsection (h)(6)(B) transfers the duties and responsibilities of the local public health officer to each employer, in essence requiring them to become public health investigators.

Response: Subsection (h)(6)(A) and (h)(6)(B) have been restructured to separate out the responsibility of health care providers or employers to report cases or suspected cases to the local health officer. Subsections (h)(6)(B) and (h)(6)(C) establish requirements for employers to conduct exposure investigations in relation to their employees and to communicate about potential exposure with other employers. This is not a transferring of duties from the local health officer. The LHO is responsible for community contact investigations which may overlap with the employer's responsibility to investigate workplace exposures, injuries and illnesses. A new sentence has been added to subsection (h)(6)(C) to require that the exposure investigation be provided to the LHO upon request.

Bonnie R. Kolesar, ARM, CCSA, Assistant Secretary, Office of Risk Management, California Department of Corrections and Rehabilitation (CDCR), by written comments dated August 20, 2008.

Comment #BRK1: CDCR disagrees with the assertion in the ISOR Informative Digest that the proposal will not result in significant costs to state agencies. There will be costs to assess whether current ATD control practices already mandated by other statutory and regulatory requirements are adequate to be compliant with Section 5199. There will be start-up, annual and on-going administrative costs associated with the vaccination program while the existing TB surveillance program has unresolved issues unrelated to Section 5199. The costs of Section 5199 compliance include training, record creation and data management. The cost balancing claim contained in the ISOR is questionable on two counts: 1) because CDCR does not receive Workers Compensation claims for influenza, there are no cost savings arising from an influenza vaccination program; and, 2) it would be difficult to figure out how to distribute any cost savings to the parts of our agency that would incur the vaccination program costs.

Response: Many requirements of Section 5199 are at least in part required by other standards, so the magnitude of costs will be in many cases less than required to initiate totally new programs because the costs will stem more from fine-tuning of existing programs. For example, the California Penal Code, Sections 6066-6009 require initial and annual or more frequent TB assessments for all correctional employees. Title 8, Section 3203 requires employers to evaluate and address hazards in the workplace through training and hazard correction. Title 8 Section 14300 et seq require recording of TB conversions.

Like many employers in the private business sector that have recognized the benefits of having fewer employee sick days due to the flu, and due to the importance of maintaining a healthy population in correctional facilities, the CDCR itself in 2008 initiated an influenza vaccination program for correctional employees and inmates. Vaccinations other than influenza are only required to be provided to employees working within the health care operations in facilities operated by CDCR, not to all correctional employees. Many health care workers are already vaccinated for mumps, measles, rubella, and varicella. Boosters of tetanus, diphtheria and acellular pertussis vaccine are typically recommended to be provided every 10 years. As discussed in the ISOR, the cost of immunization is low relative to the cost of disease. Providing these vaccinations permits the employer to reduce the susceptibility of its workforce to these diseases, such as chicken pox, which appear sporadically, and to pertussis, which is a re-emerging disease.

The Board agrees that in most instances influenza is not a disease eligible for workers compensation benefits. The ISOR reference to workers compensation savings refers instead to other ATDs whose etiology can often be determined to be work related such as TB, chicken pox, and meningitis.

Comment #BRK2: The vaccination program raises issues of medical confidentiality, responsibility of adverse impacts of vaccinations, impingement on CDCR pre-employment vaccination requirements, and impact on public sector bargaining obligations.

Response: The issue of medical confidentiality is addressed through modified language that limits the information to be provided regarding vaccines and immunization to the employer by the PLHCP, in subsection (h)(5)(F). A one-year delay is proposed for implementation of vaccination requirements to allow employers to deal with administrative issues in providing the vaccines, and to minimize costs to employers. This will provide additional time to state agencies to integrate the vaccination program with other requirements.

Comment #BRK3: The CDCR's custody functions relating to inmate health care have been diverted to a receivership by the Federal courts; the Receiver's responsibilities and span of organizational control are intertwined with that of the CDCR but with independent authority. Therefore adoption of the relevant proposals should be postponed until the Board has received the Receivership's comments, if any.

Response: The Receivership has not indicated any objections to Section 5199 to date. Section 5199 applies to employee health and safety, not to the inmate health care responsibilities that are the purview of the Receiver. The requirements of this standard are consistent with general public health recommendations.

Barbara Materna, Ph.D., CIH, Chief, Occupational Health Branch, California Department of Public Health, by written and oral comments received at the August 21, 2008, Public Hearing.

Comment BM#1: The California Department of Health (CDPH) voices its strong support for the ATD standard, the promulgation of which is an important and necessary step to ensure that California's health care, laboratory, public health, correctional facility and other workers at risk for contracting aerosol transmissible diseases have enforceable protections and employers have clear direction. Over the past years the CDPH has responded to many situations involving workers who have contracted ATDs or have been potentially exposed to aerosol transmissible pathogens, including investigations involving brucellosis, exposure to live anthrax spores, TB, Q-fever, and seasonal influenza. It is now time for a comprehensive approach, and Cal/OSHA has conducted an extremely thorough and thoughtful advisory process to involve all potentially impacted stakeholders in the development of the proposed standard, identify current "best practices" in infection control and review the scientific basis for the prevention measures required. CDPH anticipates working closely with Cal/OSHA to support effective implementation of the standard after its adoption.

Response: The Board thanks Ms. Materna for her comments and recognizes the support the CDPH has provided to the Division in developing this standard.

Bill Taylor, CSP, Safety Manger, City of Anaheim Risk Management, by written comment dated August 15, 2008, and oral comment received at the August 21, 2008, Public Hearing.

Comment #BT1: In subsection (a), scope, correctional facilities are broadly incorporated, from the very large state prisons to the far smaller facilities like our City jail. Jail population, cell population, length of stay and the proximity of the inmates are key factors that must be evaluated to assess the true risk of transmission of an ATD in a correctional facility. At our City jail, each detainee is medically screened and referred out to a County jail or hospital as appropriate. While it would thus appear we should qualify as a “referring employer, under this regulation our detention facility staff is still mandated to comply with all of the other requirements of the regulation. The City of Anaheim proposes instead that correctional facilities that meet the following conditions would not be required to comply with the standard: screen detainees pursuant to the guidelines in Appendix F and house less than an average of 30 inmates with each inmate in residence for less than an average of 3 days.

Response: The City of Anaheim jail, as described by Mr. Taylor, fits the definition of a referring employer. Referring employers *do not* have to comply with all the requirements of the standard. As is made clear in subsection (a)(3), Application, a referring employer is required only to comply with the provisions of subsection (a), subsection (c), and subsection (j) and some parts of other subsections referenced in subsection (c). The Board does not agree with the proposal to exclude certain correctional facilities from the standard as this would leave correctional facility employees at risk of exposure to ATDs.

Comment #BT2: Subsection (a), by placing maintenance employees who perform routine HVAC work on facilities that house inmates in the same category as correctional officers, grossly overstates the risk maintenance employees have of acquiring an ATD. Maintenance operations on correctional facilities should not be covered by this standard if the facilities meet the conditions described in Comment #BT1.

Response: The reference in subsection (a) to maintenance operations involving air-handling systems has been changed to clarify that the air-handling systems addressed in the standard are those connecting to AII rooms or areas, or laboratory areas, or other areas reasonably anticipated to be contaminated with aerosol transmissible pathogens. It is then up to the employer to determine whether there is occupational exposure, and whether occupational exposure has been prevented through decontamination procedures. For example, an employee doing maintenance activities in an AIIR that is occupied by a patient with active tuberculosis would be considered to have occupational exposure. An employee doing the same maintenance activity when the room is no longer occupied and it has been decontaminated and ventilated, might not have occupational exposure.

The situation described in the comment, where a person is only held in the City Jail for a short period of time, might not create a situation where the air handling systems are considered a reasonable source of exposure to ATPs, particularly if maintenance activities do not take place within a short period of time after the person has left the area.

Comment #BT3: It is impractical to expect respiratory hygiene/cough etiquette recommendations to be followed with non-compliant detainees.

Response: The respiratory hygiene/cough etiquette requirement of subsection (c)(2) clearly states it is operative only to the extent reasonably practical. The Board expects that while it may be futile to insist that hostile, combative detainees use cough etiquette, many other detainees would comply with appropriate requests from correctional officers.

Comment #BT4: Police officers have only very limited exposures for short durations to arrested persons, so there is little chance for TB conversion. In fact, in the past five years we have not had a case when a police officer was exposed to an ATD and then tested positive for the disease. A Latent TB Infection (LTBI) surveillance program for our 400 police officers and 17 correctional officers would cost over \$20,000 annually, allowing an hour per test. Police service operations where personnel are classified as referring employers need not provide surveillance of LTBI infection.

Response: Whether or not an employee must be in an LTBI surveillance program is dependent upon whether or not the employee has occupational exposure to cases of or suspected cases of TB. A modification has been proposed to subsection (a)(1)(C) to further clarify which police services are included within the scope of the standard. In addition, an employer must determine which employees have occupational exposure as defined in subsection (b). In assessing employee exposure, an employer may, for example, identify those officers who perform higher risk activities, such as screening of detainees for infectious diseases or transporting detainees needing medical care, as being the employees who have occupational exposure. The employees who are determined to be at increased risk are the only ones to whom medical services or other components of this standard must be provided.

Comment #BT5: In regard to the vaccination requirements of subsection (h)(5), not one City of Anaheim police officer or firefighter has contracted one of the listed ATDs via occupational exposure. Only influenza vaccination should be on the list, and administering the influenza vaccination will cost the city over \$20,000 annually.

Response: The only vaccine required by this standard for non health care workers is the influenza vaccine. As indicated in the ISOR, influenza vaccine is an extremely effective measure in preventing productivity loss and other costs associated with employee absenteeism. Further, the commenter estimated the employee time spent in receiving the vaccine to be one hour per employee. However, employers who sponsor flu vaccine clinics have indicated that the time an employee spends from start to finish, is typically less than 15 or 20 minutes, even when there is some waiting time. Employers may also choose to provide influenza vaccine through an employer-paid health plan, so long as the employee is not charged a co-payment, which is currently the case for many health plans. The ISOR contains additional discussion of influenza vaccination.

Elizabeth A. Treanor, Director, Phylmar Regulatory Roundtable, by written comments dated August 20, 2008, and oral comments received at the August 21, 2008, Public Hearing.

Comment #ET1: Phylmar Regulatory Roundtable (PRR) supports the exclusion from the standard of medical specialty practices that meet the specifications for exclusion contained in subsection (a)(2)(B) but believes further clarification is necessary. Many employers provide on-site occupational health clinics for employees. Occupational health clinics that meet the criteria for exclusion (i.e., have written screening procedures and refer employees to an appropriate

medical provider), should be specifically mentioned in the subsection so there is no confusion in the general industry workplace about application of the subsection in the workplace. Based upon the number of queries received by PRR, the current language is not clear with respect to occupational health clinics. The subsection should begin, “Outpatient medical specialty practices, including employers on-site occupational health clinics....”

Response: A definition of medical specialty practice is proposed to be included in subsection (b), which would include any medical practice other than one that is primary care, general medicine or family practice. Further enumeration of the different types of medical specialties would be unwieldy and is unnecessary to understanding the application of this section. Each occupational health clinic, if it is not a primary care, general medicine, or family practice, will need to determine for itself whether it treats or diagnoses ATDs. If it does not, and it has screening procedures meeting the requirements of subsection (a)(2)(B), then it can come under this exemption. Additional discussion of this provision, as modified, is included in response to comment #BK3.

Comment #ET2: PRR recommends adding a new exception to subsection (a)(2) for voluntary or collateral duty first aid. Paramedic and emergency medical services are specifically included in the standard but voluntary and collateral duty first aid are not explicitly excluded. PRR has received a number of queries regarding the applicability of Section 5199 to employees who perform first aid, so we recommend the addition of a new exception to eliminate potential confusion.

Response: The ISOR states this standard was developed to address the risks to health care workers and workers in other high-risk environments due to exposure to aerosol transmissible pathogens, such as the agents which cause tuberculosis (TB). Unlike the bloodborne pathogens standard, which broadly applies wherever there is occupational exposure, this proposed standard only applies in the facilities, services and operations specifically identified. Incidental delivery of first aid outside of these identified environments is not included within the scope of this standard. *Paramedic* and *emergency medical services* are defined and regulated in California codes and do not include ancillary first aid providers. Therefore, it would be confusing to specifically exclude a group of employees who are not working within the scope of the proposed standard.

Kevin Bland, representing California Framing Contractors Association (CFCA), California Conference of Mason Contractor Associations (CCMCA), and Residential Contractors Association (RCA), Bo Bradley, Director of Safety, Health, and Regulatory Services, Associated General Contractors (AGC) of California, Bruce Wick, Director of Risk Management, California Professional Association of Specialty Contractors (CalPASC), by oral comments received at the August 21, 2008, Public Hearing.

Comment #KB1: Kevin Bland, Bo Bradley, and Bruce Wick stated that they support the comments prepared by Elizabeth Treanor.

Response: See responses #ET1 and #ET2.

Daniel C. Tappen, Supervising Industrial Hygienist, Occupational Health Program, Department of Environmental Health, County of San Diego, by written comment dated August 21, 2008.

Comment #DT1: The proposed regulation is not needed, as Section 3203, the Injury and Illness Prevention Program regulation, addresses the issues better than trying to incorporate a wide variety of infectious disease guidelines into a “one size fits all” regulation.

Response: The Board believes that the control of aerosol transmitted diseases is not addressed with sufficient specificity by Section 3203, when it comes to protecting workers in high risk environments such as health care, corrections, and other workplaces identified in this proposal. Section 5199 identifies which specific employer categories need to address this issue to protect employees and points employees to CDC and other sources of recognized recommendation for the handling of specific disease risk.

Comment #DT2: The definition in section (b) for aerosol transmissible disease as diseases or pathogens for which droplet or airborne precautions are *recommended* in Appendix A is confusing, as Appendix A, which is *mandatory*, states employers are required to follow Section 5199’s protections. Also, please clarify if the referenced diseases apply to both the airborne disease pathogen list and the droplet precaution list.

Response: The introductory language of Appendix A has been modified to clarify, consistent with the definition, that both diseases identified as requiring droplet precautions and diseases requiring airborne infection isolation are included within the scope of this standard. In addition, the term “recommended” in the definition has been changed to “required.”

Comment DT3: The term “*outpatient medical specialty practices*” in subsection (a)(2)(B) is not defined anywhere in the regulation.

Response: A definition of the term “medical specialty practice” is proposed to be included in this section. Please see comment #ET1 for further discussion.

Comment #DT4: Subsection (e)(5)(D) on ventilation rates for airborne infection isolation rooms is more restrictive than the more flexible CDC recommendations which only recommends 12 air changes per hour (ACH) if feasible. The flexibility of the CDC recommendations is especially important to older facilities for whom upgrading from 6 ACH to 12 ACH is particularly infeasible. The 6 ACH comes from ASHRAE and AIA criteria for isolation or treatment rooms, and there are no studies showing employees are at risk at the lower ACH. When this section discusses necessity for negative pressure to be maintained in AI rooms or areas, it does not specify the differential in pressure between the AI room and adjacent areas. The pressure differential is more significant for employee health than the ACH question. Currently, CDC’s TB criteria recommend, but do not insist on, ≥ 0.01 inches water gauge, while older CDC numbers and the formerly proposed Fed/OSHA TB standard called for a 10% greater exhaust flow than supply flow to the AI room with a minimum of 50 CFM differential. This latter recommendation should be the minimum requirement in the ATD standard with ≥ 0.01 inches water gauge required if feasible.

Finally, this subsection of the proposed regulation calls for compliance with the CDC Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings for hoods, booths, tents, etc. Reference to the CDC document here is confusing, as it appears

Cal/OSHA is deviating from CDC recommendations for AI rooms but not for hoods, booths, etc. Again, using Section 3203 would be preferable.

Response: In regard to isolation rooms and in regard to hoods, booths, etc., this subsection *does* follow the CDC recommendations and it has the same flexibility, allowing for AIIR, no matter the age of the facility, to achieve the required ventilation rate in part through air cleaning technology, so long as 6 ACH are maintained. Both ACH and negative pressure are necessary to reduce the concentration of pathogens within the room and to protect persons located outside of the room, since the negative pressure of these rooms may be overwhelmed by cross drafts and other air movements when doors to the rooms are opened, etc.

Generally, as stated explicitly in subsection (e)(1), all engineering controls are required to follow recommendations in the CDC TB guideline. The purpose of specifically enumerating the requirements for AIIR is to make clear which of the CDC recommendations are specifically incorporated. The proposal does not incorporate a specific negative pressure value because negative pressures as low as 0.01 or 0.001 in. of water gauge are difficult to measure accurately, and may not be meaningful. It is also not always possible to measure accurately a 50 cubic feet per minute (CFM) difference in supply and exhaust rates. There is no conflict between the provisions specifically adopted into the standard, and the general guidance provided by the referenced document.

See also the response to comment #RR14 regarding the relationship between the guideline and the standard.

Comment #DT5: Subsection (d)(2) on the ATD Exposure Control Plan does not mention the most important part of an Exposure Control Plan, *risk assessment*. Risk assessment allows for risk classification of employees so that appropriate control measures can be implemented based upon level of risk. It is through risk assessment that many of the requirements of subsection (d), such as the list of job classifications with ATD exposure, can be addressed. Is it correct that for respiratory protection, a low risk classification (at least by CDC TB guidelines) would fall under Cal/OSHA voluntary use criteria? Also, is it correct that the ATD Exposure Control Plan is not required for Referring Employers?

Response: The concept of “risk assessment” is incorporated into the definition of the term “occupational exposure,” defined as “exposure from work activity or working conditions that is reasonably anticipated to create an elevated risk of contracting any disease caused by ATPs or ATPs-L...” The additional text in this definition provides guidance to the employer in identifying who is to be included in the ATD plan. An ATD plan is not required for referring employers, instead there is a reduced requirement for infection control procedures in subsection (c).

The concept of “risk assessment” is also included in the definition of high-risk procedures. Again, guidance is given by the definition, but exposure control plan administrators must assess their operations to determine which procedures fall into this category.

California TB guidance has differed from the CDC document referenced by Mr. Tappen on several issues, including frequency of TB testing for health care workers, and discharge criteria. It is not correct that risk assessment in accordance with the CDC TB guidelines controls

respirator use under this section. Respirator use is defined in subsection (g). A minimum list of activities for which respirator use is required are enumerated in subsection (g)(4). The employer may add to this list, based on their “risk assessment.” Whenever an employer requires respirator use, that use is not considered voluntary under OSHA regulation 29 CFR 1910.134 or the California equivalent, Section 5144.

The concept of risk assessment has been incorporated for laboratory operations, for which there are specific procedural guidelines in the BMBL.

Comment #DT6: The standard should not be adopted, especially after only one public comment period. I disagree with the cost estimates—the standard will have a dramatic time/cost impact on employers. If the standard is adopted, there should be a long phase in period or distant implementation date to allow employers enough time to get all the pieces in place.

Response: Section 5199 is the result of a four-year advisory process with significant input from all stakeholder groups, including participation by San Diego County. The Board believes that there is a necessity to move forward as quickly as possible with this proposal, because preparation of the health care and public safety workforce for a health care surge event, such as pandemic influenza, is critical to the ability of our state to weather such a storm. In the meantime, California workers are exposed daily to TB, pertussis, and other infectious diseases. The implementation date of the standard’s vaccination provisions is proposed to be extended for a full year, and the Board will consider other prolonged implementation periods for specific provisions of the standard. The commenter provided no specific information regarding potential cost impacts, and on review of the rulemaking file, the Board finds no basis to dispute the original analysis.

Mark Catlin, Industrial Hygienist, Bill Borwegen, Occupational Health and Safety Director, Service Employees International Union, by letter dated August 20, 2008, and oral comments provided by Mr. Catlin on August 21, 2008, at the Public Hearing.

Comment #MC1: The Service Employees International Union (SEIU) believes that it is important to protect workers against hazards posed by aerosol transmissible pathogens. The SEIU represents more than 700,000 workers in California, most of whom will gain some additional protection by the adoption of this proposal. They are pleased that California is proposing a standard to protect workers from ATDs, which takes a comprehensive approach to both airborne and droplet exposures, and covers a wide range of infectious agents.

Response: The Board thanks Mr. Catlin and Mr. Borwegen for their comments.

Comment #MC2: It is clear that home health care is included in the standard under subsection (a)(1)(A)5. The standard should also clearly include *home care* work. Home care workers provide assistance to frail elderly and disabled people in their homes, and the duties range from bathing them to preparing meals and administering medications. More than 400,000 Californians depend on home care to meet their most basic daily needs. These workers are already included as important resources in many pandemic flu preparedness plans to meet the surge in demand for home care expected either because of the flu itself or because people’s support networks have become unavailable.

Response: Most people in this society are at some risk of contracting an ATD from the people around them. Employees whose work activities bring them into close or sustained contact with other people may have some increased risk. However, inclusion of work settings within the scope of this standard was based on experience and research showing that the environments and activities included in this standard contained sufficient increased risk beyond that of typical public contact occupations.

Home health care operations provide nursing and other services in a home setting to persons who have diseases, such as TB, or are immuno-compromised, that might otherwise be provided in a hospital or skilled nursing facility. For this reason, home health care operations have been included in this standard. Risks to home care workers were discussed in advisory meetings, as were risks to employees in non-health care facilities for persons needing long-term care (such as assisted living facilities). At this time, the Board has not received sufficient evidence of increased risk to these worker populations to require their inclusion in this proposal. Section 3203, Injury and Illness Prevention Program, provides a framework for employers not included in this standard to identify, evaluate and correct any infectious disease hazards that may exist in the work place.

Comment #MC3: The commenters are concerned with the exclusion of outpatient dental clinics or offices in subsection (a)(2)(A), if they meet certain criteria. These establishments need to be included in the standard in order to ensure that employees are trained and that patients are screened for ATDs. Also, there is no evidence that physicians have the knowledge and experience to determine whether or not a given dental procedure performed on a patient identified through the screening procedures does not pose an ATD risk to employees under subsection (a)(2)(A)3. If procedures are to be performed on a patient with an ATD, the employees should be protected by the requirements of the standard.

Response: See the response to comment #BK2.

Comment #MC4: The commenters believe that the exclusion for medical specialty practices in subsection (a)(2)(B) does not ensure that the screening procedures required by the exclusion will be conducted. Including these workplaces within the scope of the standard is the only way to ensure that employers implement screening procedures and to ensure that employees are trained.

Response: See the response to Comment #BK3.

Comment #MC5: The commenters are pleased to see that California is proposing to include within the definition of Airborne Infectious Disease (AirID) “novel and unknown pathogens.” Treating novel and unknown pathogens as potentially transmitted by airborne means is an appropriate precautionary approach that is necessary to protect exposed workers. The commenters also support the note that explicitly includes pandemic influenza strains as novel pathogens.

Response: The Board thanks Mr. Catlin and Mr. Borwegen for this comment.

Comment #MC6: The commenters support the definition of exposure incident, with the clarification that it includes situations in which the employee exposure is not in the presence of the individual with known or suspected disease – “for example a worker with proper PPE

entering a vacated airborne infection isolation room before proper decontamination has occurred.”

Response: Language has been added to the definition of exposure incident to clarify that it includes exposure to a source of ATPs such as a contaminated room or air ducts.

Comment #MC7: The commenters believe that this standard should apply to home care workers. The commenters believe that either the definition of health care worker should be changed, or a new definition should be added to define home care workers.

Response: See response to comment #MC2.

Comment #MC8: The commenters object to the phrase in subsection(c)(5)(C) which would limit the circumstances in which a referring employer would be required to provide employees with respiratory protection when entering a room or area in which a person is waiting for referral, to those circumstances in which the person "is not compliant with source control procedures." This language is vague and difficult to interpret, and is insufficiently protective of worker health. What are the criteria for determining if a person is compliant? The standard should include a requirement for the use of respiratory protection whenever a worker enters the room or area of a person awaiting referral, with no exception.

Response: See response to comment #BK5.

Comment #MC9: The commenters believe that to maximize the protection of employees who will enter areas where persons are awaiting referral, the case or suspected case should require that the referral person be provided with a procedure mask, as part of the source control measures.

Response: See response to comment #BK6.

Comment #MC10: The language in subsection (c)(6)(B) that would require that referring employers provide medical services in accordance with subsections (h)(6) through (h)(9) is too limited in requiring the services only for RATD cases or suspected cases. The commenters state that diseases reportable under Title 17 do not include avian influenza, SARS, monkey pox and novel and unknown pathogens. There is no scientific reason to exclude “unreportable” diseases from procedures for exposure incidents.

Response: See response to comment #BK7.

Comment #MC11: The commenters support the requirement in subsection (c)(7) that employees covered by this standard receive training at the time of initial assignment and at least annually thereafter. New language should be added requiring additional training when there are changes in the workplace or new information becomes available. It is important that workers have the new information as soon as possible.

Response: The Board agrees that changes in procedures or in the workplace that potentially affect employee exposures should require additional training, and language has been added to the proposed subsection.

Comment #MC12: Subsection (c)(7)(H) which requires training on vaccines, should be expanded to include training on treatment options such as antibiotics and antiviral drugs which may be used to protect workers after exposure incidents, or as prophylaxis.

Response: See response to comment #BK9.

Comment #MC13: The development of an exposure control plan is a necessary and critical function of the standard. The proposal places responsibility for the development of the plan on the employer but is silent on the sources of information and expertise that the employer should seek out in preparing the plan. Frequently workers and their unions represent rich and useful sources of information, knowledge and input that can assist the employer and development of the plan. The commenters therefore recommend requiring that employers involve workers and their unions in developing the plan. The comment includes proposed language requiring the employer to develop a written plan of action regarding the implementation of employee participation, and to consult with non-managerial employees and their representatives.

Response: See response to comment #BK10.

Comment #MC14: The commenters suggest that the language from the Bloodborne Pathogens standard regarding review of the plan be incorporated into subsection (d)(3). In addition to reviewing and updating the plan annually, the language proposed by the commenters would require the plan to be reviewed and updated whenever necessary to reflect new information or circumstances that significantly affect occupational exposure, to reflect new or revised employee positions with occupational exposure, and to reflect changes in technology that eliminate or reduce exposure. The commenters also suggest requiring that the employer document annually the consideration and implementation of appropriate commercially available technology designed to eliminate or minimize occupational exposure.

Response: See response to Comment #BK11.

Comment #MC15: The commenters agree with subsection (d)(4) that the exposure control plan should be made available to employees and employee representatives for examination and copying. The proposal should include the language from the bloodborne pathogens standard that refers to the records access provision of Access to Employee Exposure and Medical Records.

Response: The Board agrees with this comment, and language has been added to subsection (d)(4) and (j)(4) effectively referencing the record access provisions of Section 3204, Access to Employee Exposure and Medical Records.

Comment #MC16: The commenters support the requirement in subsection (e)(1) that employers use feasible engineering and work practice controls to minimize employee exposure. It would be useful to provide definitions and examples of engineering and work practice controls.

Response: The Board believes that this section establishes performance requirements for employers. Employers covered by this section may have very different operations, and it would be impossible for this standard to include examples from all of the different environments. The

Board believes that these examples are more appropriately placed in educational materials to be developed by the Division to assist in the implementation of this standard.

Comment #MC17: The commenters suggest that subsection (e)(1)(A) be revised to clearly describe the hierarchy of controls used in occupational safety and health, and include a discussion of engineering controls for ATPs. The commenters included a reference to material available from the Areobiological Engineering/Architectural Engineering Department at Penn State University.

Response: Subsection (e)(1) clearly adopts a hierarchy of controls. In many operations under this standard, engineering and work practice controls are interwoven. For example, early case identification and limiting contact with a potentially infectious patient is a work practice control, including placing the patient in a separate room or area. The specifications for the ventilation to be provided to that room or area are engineering controls. Examples of control measures and references are more appropriately provided through educational material that will be developed to support implementation of the standard.

Comment #MC18: The term “susceptible” should be removed from proposed subsection (e)(5)(B)2.e. which requires respirator use by all “susceptible” employees who enter an AII room or area where AirID cases or suspected cases are housed. The commenters state that the term “susceptible” is undefined and should be removed to avoid confusion. All workers who enter the room or area should be provided with respiratory protection, as well as other forms of PPE.

Response: See response to Comment #BK14.

Comment #MC19: The commenter supports the requirement in the Exception to subsection (e)(5)(C) that when high hazard procedures are performed outside of airborne infection isolation rooms or areas, that all employees working in the room or area where the procedure is performed use respiratory protection. The commenter believes that this requirement should also include all necessary PPE.

Response: The Board agrees that personal protective equipment must be provided to anyone in the area where a high hazard procedure is performed. Language has been added to require that persons not performing the procedure be excluded from the area where these procedures are being performed, unless the person is provided with the PPE and respiratory protection required for persons performing the procedure.

Comment #MC20: The commenters disagree with subsection (g)(3)(A) which requires that the minimum level of respiratory protection provided under this standard be at least as effective as an N95 filtering facepiece respirator. The commenters believe that the minimum level of protection should be a P100 filtering facepiece respirator equipped with an elastomeric facepiece seal. The commenters referred to several articles that they believe raise questions about the effectiveness of N95 filtering facepiece respirators in protecting employees against infectious aerosols. (See Lee, et al 2008, Balazy et al 2006, and Eninger et al 2008).

Response: See response to comment #BK16.

Comment #MC21: The commenters support the requirement in subsection (g)(3)(B) that a PAPR equipped with HEPA filters be provided to workers who perform high hazard procedures and work on cadavers. This requirement should be modified to permit the use of a respiratory protection device providing equivalent or better levels of protection, in order to permit the use of supplied air respirators or other respirators. Also, employers should be required to provide a PAPR to employees who have been determined to be medically incapable of wearing a filtering facepiece respirator but who are capable of wearing a PAPR.

Response: See response to comment #BK17.

Comment #MC22: The commenters disagree with the Exception to subsection (g)(6)(B)3, that permits the repeat fit-testing interval to be increased to every two years until January 1, 2014, for employees who do not perform high hazard procedures. The commenters state that although the proposal mentions a NIOSH study that will provide information on appropriate fit-test intervals, there is no evidence available at this time that supports a fit-test interval longer than one year, and there is evidence that supports the requirement for annual fit testing. Further, the commenters cite several studies that show that a respirator that has passed a fit test for an individual worker provides better protection than one that has not (Lee 2004, Coffey 2004, Lawrence 2006).

The commenters also cite evidence in the OSHA record supporting annual fit-testing, and a letter from NIOSH Director John Howard, supporting an annual fit-test interval. The commenters disagree that the issue of cost to employers of annual fit-testing should be a reason to increase the fit-test interval, given the lack of scientific support for a longer interval. The commenters further state that this Cal/OSHA provision would be less effective than federal OSHA.

Response: See response to comment #BK18.

Comment #MC23: The commenters support the activities required in subsections (h)(6)(A) and (h)(6)(B) in response to exposure incidents. These activities should not be restricted to diseases that are reportable under Title 17 of the California Code of Regulations, which the commenter states does not include avian influenza, SARS, monkeypox and novel or unknown pathogens. There is no scientific rationale for eliminating these diseases from requirements for exposure incidents.

Response: See response to comment #BK19.

Comment #MC24: The commenters strongly support the training requirements in this proposal, including requirements that the training be done by a knowledgeable person, and that training material be appropriate in content and vocabulary to the education level, literacy and language of the employees, and that workers have an opportunity for interactive questions and answers with the person conducting the training. Similar training requirements that were in the OSHA Bloodborne Pathogens standard were important in reducing the rate of occupationally acquired Hepatitis B infection.

Response: The Board thanks the commenters for their support.

Comment #MC25: Subsection (j)(4)(A) should include a requirement that employees and employee representatives be afforded access to all records, other than employee medical records, that are required to be maintained under this standard. Lack of access may hamper the ability of employees and their representatives to utilize their knowledge and expertise to advance safety and health measures in their workplace. The standard should include provisions for access in accordance with the Access to Employee Exposure and Medical Records standard.

Response: The Board agrees that access to records of program implementation, other than employee medical records, would enhance the ability of employees and their representatives to participate in reviewing and updating the employer's infection control procedures. Section 3204, Access to Employee Exposure and Medical Records establishes a reasonable framework for providing these records. Therefore language has been added to subsection (j)(4)(B) to require that access be provided to employees and their representatives in accordance with Section 3204.

Comment #MC26: A section should be added to address "housekeeping," to include such issues as disposal of infectious waste and patient-care equipment, and environmental cleaning and disinfection.

Response: See response to comment #BK21.

Comment # MC27: A subsection should be added regarding labels and signs to alert and warn employees about exposure potential related to equipment, objects, rooms or areas. This would assist in reducing exposure incidents and protecting workers from infection.

Response: See response to comment #BK22.

Azita Mashayekhi, M.H.S., Industrial Hygienist, Safety and Health Department, The International Brotherhood of Teamsters, by letter dated August 21, 2008.

Comment #AM1: The International Brotherhood of Teamsters (IBT) represents 1.4 million workers in the United States and Canada, including thousands employed by the private sector and state and municipal governments in California, who are at increased risk of exposure to aerosol transmissible pathogens. These workers are employed in hospitals and other health care facilities and operations, correctional facilities, firefighters, and emergency responders, police services and laboratory workers. Adoption of an aerosol transmissible disease standard is necessary to ensure the mandate of the California Labor Code Section 6400 that "Every Employer shall furnish employment and a place of employment that is safe and healthful for the employees therein." The IBT strongly supports the intent of the standard, to protect employees from exposure to infectious aerosols, such as the agents that cause tuberculosis and Severe Acute Respiratory Syndrome (SARS) and pertussis. The commenter is also reassured by the fact that the proposal was developed with the assistance of a broad spectrum of stakeholders.

Response: The Board thanks Ms. Mashayekhi for her comments.

Comment #AM2: The definition of "home health care" in subsection (a)(1)(A) should include home care work performed by personal attendants. Home care workers provide assistance to frail elderly and disabled people in their homes, and the duties range from bathing them to preparing meals and administering medications. More than 400,000 Californians depend on home care to

meet their most basic daily needs. These workers are already included as important resources in many pandemic flu preparedness plans to meet the surge in demand for homecare expected either because of the flu itself or because people's support networks have become unavailable.

Response: See response to comment #MC2.

Comment #AM3: The commenter agrees with the definition of Airborne Infectious Disease (AirID) as it extends to a disease process caused by a novel or unknown pathogen. This definition addresses her concern that pandemic influenza virus may be transmitted via an airborne route, and the "confusion on the federal level surrounding the use of respirators versus facemasks during a pandemic." It supports the IBT position in favor of mandatory workplace requirements for protecting health care, emergency response, and other workers during a pandemic influenza outbreak.

Response: The Board thanks the commenter for her support.

Comment #AM4: The phrase in subsection (c)(5)(C) would limit the circumstances in which a referring employer would be required to provide employees with respiratory protection when entering a room or area in which a person is waiting for referral, to those circumstances in which the person "is not compliant with source control procedures." This is vague and difficult to interpret, and is insufficiently protective of worker health. The commenter asked what the criteria are for determining if a person is compliant. Entry into an area where a person who is a case or suspected case of AirID is located, even while awaiting referral, constitutes occupational exposure and an "elevated risk," which necessitates ensuring that workers are protected from exposure, independent of whether the person is utilizing source control measures. Also, to maximize protection, the person awaiting referral should be provided with procedure or surgical masks. The standard should include a requirement for the use of respiratory protection whenever a worker enters the room or area of a person awaiting referral, with no exception.

Response: In regards to the first part of the comment, see the response to comment #BK5.

In regards to requiring procedure masks for persons awaiting referral, source control measures as recommended by the CDC and by advisory committee participants permit the use of masks or, as an alternative, tissues and hand hygiene materials to control respiratory secretions. There are some circumstances in which a patient cannot use a mask. The proposal leaves it to the institution to determine the most effective means for controlling respiratory secretions in that setting.

Comment #AM5: Subsection (c)(7) should include a requirement that additional training be provided when there are changes in the workplace or new information becomes available. The language used in Section 5193, Bloodborne Pathogens, provides a good model. It is important that workers have the new information as soon as possible.

Response: The Board agrees that changes in procedures or in the workplace that potentially affect employee exposures should require additional training, and language has been added to the proposed subsection.

Comment #AM6: Subsection (c)(7)(H) which requires training on vaccines, should be expanded to include training on treatment options such as antibiotics and antiviral drugs which may be used to protect workers after exposure incidents, or as prophylaxis.

Response: See response to comment #BK9.

Comment #AM7: The development of an exposure control plan is an essential component of the standard. The proposal places responsibility for the development of the plan on the employer but is silent on the sources of information and expertise that the employer should seek out in preparing the plan. Frequently workers and their unions represent rich and useful sources of information, knowledge and input that can assist the employer and development of the plan. The commenter therefore recommends requiring that employers involve workers and their unions in developing the plan, and suggests the following language:

“An employer, who is required to establish an Exposure Control Plan shall develop a written plan of action regarding the implementation of employee participation. The employer shall consult with non-managerial employees responsible for direct patient care who are potentially exposed to ATDs and ATPs and their representatives on the identification, evaluation, and selection of effective engineering, work practice controls and personal protective equipment and shall document the consultation in the Exposure Control Plan. This participation shall include the required annual reviews of the plan.”

Response: See response to comment #BK10.

Comment #AM8: The commenter supports the requirement in subsection (d)(3) for annual review of the plan by the program administrator and employees regarding effectiveness of the plan in their work area. Additional language should specifically require employer to actually modify the plan based upon the findings and employee input obtained in the annual review. Also, the proposal should include a requirement that the plan be modified whenever there is new information or circumstances that significantly impact on the health and safety of workers.

Response: See response to comment #BK11.

Comment #AM9: The commenter supports the requirement in subsection (d)(4) that the exposure control plan be made available to employees and their representatives for examination and copying. The commenter supports adding a requirement establishing the maximum timeframe, preferably by the end of the next business day. The commenter also suggests adding a requirement that the copy be provided to requesters at no cost to them.

Response: See response to comment #BK12.

Comment #AM10: In regards to subsection (e)(1), a definition of engineering controls and work practice controls should be provided in order to clarify what is meant by each of these control measures. An appendix could accomplish this. Section (e)(1)(A) should not include the use of personal or respiratory protection in the note on work practices. The commenter also suggests requiring personal protective equipment for employees who transport ATD cases or suspected cases.

Response: See response to comment #BK13.

Comment #AM11: The term “susceptible” should be removed from proposed subsection (e)(5)(B)2.e. which requires respirator use by all “susceptible” employees who enter an AII room or area where AirID cases or suspected cases are housed. The commenter states that the term “susceptible” is undefined and should be removed to avoid confusion. All workers who enter the room or area should be provided with respiratory protection, as well as other forms of PPE.

Response: See response to comment #BK14.

Comment #AM12: The commenter supports the requirement in the Exception to subsection (e)(5)(C) that when high hazard procedures are performed outside of airborne infection isolation rooms or areas, that all employees working in the room or area where the procedure is performed use respiratory protection. The commenter believes that this requirement should also include all necessary PPE.

Response: See response to comment #BK15.

Comment #AM13: Subsection (g)(3)(a) proposes that a respirator at least as effective as an N95 filtering facepiece respirator become the minimum level of respiratory protection under this standard. The commenter believes that the minimum level of respiratory protection should be an N100. The commenter referred to several articles that raise questions about the effectiveness of N95 filtering facepiece respirators in protecting employees against infectious aerosols. (See Lee, et al 2008, Balazy et al 2006, and Eninger et al 2008).

Response: See response to comment #BK16.

Comment #AM14: The commenter supports the requirement in subsection (g)(3)(B) that a PAPR equipped with HEPA filters be provided to workers who perform high hazard procedures and work on cadavers. This requirement should be modified to permit the use of a respiratory protection device providing equivalent or better levels of protection, in order to permit the use of supplied air respirators or other respirators. Also, employers should be required to provide a PAPR to employees who have been determined to be medically incapable of wearing a filtering facepiece respirator but who are capable of wearing a PAPR.

Response: See response to comment #BK17.

Comment #AM15: The proposed Exception to subsection (g)(6)(B)3 seeks to circumvent the requirement to conduct annual fit testing of respirators by permitting the repeat fit testing interval to be increased to every two years until January 1, 2014. The commenter states that despite possible studies by NIOSH related that may relate to fit testing intervals, there is no evidence that supports a two-year fit testing interval versus annual fit testing.

Response: See response to comment #BK18.

Comment #AM16: The commenter supports the activities required in subsections (h)(6)(A) and (h)(6)(B) in response to exposure incidents. These activities should not be restricted to diseases that are reportable under Title 17 of the California Code of Regulations, which the commenter

states does not include avian influenza, SARS, monkey pox and novel or unknown pathogens. There is no scientific rationale for eliminating these diseases from requirements for exposure incidents.

Response: See response to comment #BK19.

Comment #AM17: The commenter believes that subsection (j)(4)(A) should include a requirement that employees and employee representatives be afforded access to all records, other than employee medical records, that are required to be maintained under this standard. Lack of access may hamper the ability of employees and their representatives to utilize their knowledge and expertise to advance safety and health measures in their workplace. The standard should include provisions establishing a deadline by which records are to be provided to a requester, such as by the end of the next business day. The records should be provided to employees and their representatives at no cost to them whenever they are requested.

Response: See response to comment #BK20.

Comment #AM18: A section should be added to address “housekeeping,” to include such issues as disposal of infectious waste and patient-care equipment, and environmental cleaning and disinfection.

Response: See response to comment #BK21.

Comment #AM19: A subsection should be added regarding labels and signs to alert and warn employees about exposure potential related to equipment, objects, rooms or areas. This would assist in reducing exposure incidents and protecting workers from infection.

Response: See response to comment #BK22.

Danielle Lucido, Staff Attorney and Suzanne Murphy, Executive Director, Worksafe, by letter dated August 21, 2008.

Comment #DL1: Worksafe is a California-based non-profit organization dedicated to promoting occupational safety and health through education, training, technical and legal assistance and advocacy. They urge the adoption of Section 5199 with minor changes. A standard to protect workers against aerosol transmissible diseases is long overdue. Since the resurgence of tuberculosis in the 1980’s, OSHA and Cal/OSHA have relied on policies and procedures to piece together protective measures that have not been adequate to address tuberculosis. A standard is needed to address tuberculosis and other diseases, including the possibility of pandemic flu.

Response: The Board thanks Ms. Lucido and Ms. Murphy for their comments.

Comment #DL2: The proposal would require that the minimum level of respiratory protection would be an N95 respirator. Recent studies have found that existing N95 respirators, which partially rely on electrostatic charges to filter the air, may not provide enough protection for aerosols smaller than 0.3 microns, which is the size at which respirators are tested. There is also controversy about whether a filtering facepiece respirator is as effective as a respirator with a rigid plastic facepiece. Different types of germs have different infective doses, and remain viable

for different periods of time in the air, and may be present in a broad size range of particles. The minimum level of respiratory protection under this standard should be provided via an N, P or R 100 filter, and if a powered air-purifying respirator is not used for high hazard procedures, then the minimum class of respirator should be an elastomeric facepiece respirator with an N, P or R 100 cartridge.

Response: See response to comment #BK16.

Comment #DL3: The commenters disagree with the exception to annual fit-testing permitted in subsection (g)(6)(B)3. In the absence of any evidence to the contrary, an annual fit-test is an appropriate interval.

Response: See response to comment #BK18.

Comment #DL4: Proposed Section 5199 [subsection (e)(1)(C)] only requires that employers *consider* the use of barriers or air handling systems in ambulances and other vehicles. Barriers and air handling systems should be *required* in ambulances. Emergency medical personnel provide life-saving treatment and transport to people who may have a variety of underlying illnesses, and deserve effective protection.

Response: Subsection (e)(1) requires employers to implement feasible engineering controls, which would include feasible barriers and ventilation systems. Subsection (e)(1)(C) was added as a result of discussion at advisory meetings, in which some participants reported that patient transport areas in ambulances may not be separate from the area where the driver is located. Participants also reported that patient transport areas may not be ventilated, or may not be adequately ventilated, and recent barrier designs may increase the problem. A number of practical issues were also raised regarding installation of partitions and ventilation systems in existing vehicles. For this reason, the proposal requires employers to look into the feasibility of implementing engineering controls in ambulances and other vehicles used for transporting AirID cases and suspected cases, and to document this assessment. This assessment is further required to be reviewed annually in accordance with subsection (d)(3). Subsection (e)(1)(C) enhances the requirement for employers to implement feasible engineering controls by requiring the employer to effectively annually assess the feasibility of their use. The Board believes that this is a reasonable approach to encouraging the use of barriers and ventilation systems.

Comment #DL5: The commenters support requirements that exposure be communicated to employees and other employers. Some of the proposed timeframes may be too long, and should be reconsidered and shortened, if possible. For example, if a worker were exposed to bacterial meningitis, that worker should be provided with antibiotics immediately.

Response: The proposed language has been changed to reflect the differences in the window necessary for initiating appropriate medical intervention, and to set a maximum timeframe for communication that is based on the need to start exposure investigations in a timely manner. A note has also been added to address different considerations for timely communication. See Comment #RR22 for further discussion.

Comment #DL6: The commenters support the requirement that powered air purifying respirators be used for high hazard procedures, they believe high hazard procedures should include suctioning.

Response: The definition of high hazard procedures in the standard includes some examples, however, the examples are not intended to be a complete list of all high hazard procedures. It is up to the employer, under subsection (d)(3)(C), to list high hazard procedures that are performed in the facility. This list is subject to review by the employer and employees.

Kevin White, California Professional Firefighters, by electronic mail dated August 19, 2008.

Comment #KW1: In reference to subsection (g)(3) California Professional Firefighters believes that an N95 respirator does not provide sufficient protection against infectious aerosols to firefighters and other emergency medical services personnel. Although an N95 respirator may be adequate in a hospital environment with other control measures, in a pre-hospital setting, it is never known what pathogen or route of exposure may be encountered. Therefore the highest level of PPE should be available, and CPF recommends mandating a minimum of a P-100 filtering facepiece respirator. The commenter provided several references. Further, a higher level of respiratory protection, including a full or half facepiece air purifying respirator (APR) or PAPR with HEPA filter/canister, should be available to all responders.

Response: Emergency medical services (EMS), such as paramedics, may be exposed to high concentrations of aerosols, particularly when performing high hazard procedures, or being exposed to aerosols generated by intubated patients. It is also possible that emergency medical procedures provided in the context of injuries and accidents may involve wet or oily environments that would compromise the integrity of N95 filter materials, or of the sealing surfaces of the respirator.

The standard as originally proposed required the use of PAPRs for high hazard procedures, unless it would interfere with the performance of the task, in which case a respirator at least as effective as an N95 would be required. However, in these emergency operations, it may not be feasible to provide a PAPR. Therefore, in order to address the potential for higher exposures in the EMS setting, the modified proposal contains a new exception to subsection (g)(3)(B) permitting the use of P100 respirators by paramedics performing high hazard procedures when PAPRs are not used.

Lauri Thrupp, MD, and Linda Dickey, RN, MPH, CIC, Assistant director, Epidemiology & Infection Prevention, UC Irvine Healthcare, by electronic mail dated August 21, 2008.

The commenter states that her comments pertain only to “sections dealing with aerosol-transmitted contagious diseases.” The commenter further states that she has separately forwarded specific wording changes, however, those suggestions have not been received.

Comment #LT1: The overall tone of the document seems laboriously aimed at prevention of transmission from patients with known or seriously suspect disease. It would be informative background information to include introductory comment emphasizing that it is the undiagnosed or unsuspected patient that may transmit. “Such patients [are] not in negative pressure rooms and not being handled with masks (surgical or N-95) that represents virtually all of the few cases of

occupational transmission that occur. We have had no problems with infection from our known patients in airborne precautions (without PAPRs).”

Response: The proposed standard includes several provisions that are meant to reduce exposures to persons who have not yet been identified, including requiring source control procedures, early identification of cases or suspected cases, and referral of those persons to appropriate facilities. Transmission has occurred in settings where patients were not appropriately isolated after manifesting symptoms consistent with tuberculosis, and some of these cases were discussed during the advisory process. However, transmission of airborne disease has also occurred from identified cases during high risk procedures, such as SARS transmission to nurses performing intubation and suctioning prior to intubation on identified potential SARS cases, using only surgical masks or N95 respirators. In addition there is also a published report of transmission of SARS to health care workers during bronchoscopy (Ofner). Dr. Catanzaro reported transmission of tuberculosis during bronchoscopy as well (Catanzaro).

For more discussion regarding the necessity for PAPRs, please see Comment #AF1.

Comment #LT2: The draft Section 5199 and Appendices bundles patients with diseases requiring airborne or droplet precautions as all subject to requirements including PAPRs for high risk procedures. The droplet group has long been handled with Standard Precautions plus surgical (“droplet”) masks and the commenter is not aware of any clinical evidence of failure of this procedure.

Response: Subsection (g)(3)(B) requires PAPRs in a clinical setting only for high hazard procedures on cases or suspected cases of airborne infectious diseases (AirIDs). PAPRs, and respiratory protection in general, is not required for diseases for which airborne infection isolation is not required. The standard requires PAPRs for aerosol generating procedures on cadavers because those procedures, such as the use of saws, create aerosols that would not normally result from coughing and other respiratory secretions from living people.

An incorrect footnote in Appendix A of the original proposal may have created some confusion between airborne and droplet precautions. This footnote has been removed in the modified draft.

For more discussion regarding the PAPRs please see Comment #AF1.

Comment #LT3: “The draft Section 5199’s definition of high risk procedures includes suctioning, administration of aerosol medication (e.g. albuterol), as well as bronchoscopy; with other paragraphs and definitions calling for PAPRS for these.”

Response: Procedures that increase employee exposures to infectious aerosols are considered high hazard procedures. Under this standard, employers would be required to determine whether a procedure is high hazard. The examples provided are those provided by the Centers for Disease Control and Prevention and other public health authorities, and were reviewed by the advisory committee at a number of meetings. The list is not meant to be exhaustive. A procedure is only considered to be high hazard when it is performed on a case or suspected ATD case. PAPRs are only required for AirID cases. However, because high hazard procedures increase infectious aerosols, and may create an airborne exposure risk which would not be present under normal patient care circumstances, and because disease transmission, as noted by the commenter above

often occurs before a final diagnosis is made, high hazard procedures are required to be conducted in an AII room or area. The standard requires employers to determine which high hazard procedures are performed in the institution and to provide appropriate control measures.

For more discussion regarding PAPRs please see comment #AF1.

Comment #LT4: The requirement for PAPRs is “vastly overstated.” Others supporting PAPRs have quoted the Johns Hopkins Hospital TB Control Plan of 2005 which called for PAPRs with airborne precautions. The commenter refers to a statement made to her by Dr. Trish Perl, Director of Infection Control and Epidemiology at Johns Hopkins “to the effect that they have found their PAPR program to be cumbersome, impractical and difficult to administer. Therefore they are at present in the process of significantly revising this point, and will likely go back to the N-95 or equivalent guideline.”

Response: The Johns Hopkins respiratory protection program has been revised and posted. It continues to maintain that the PAPR is the primary respirator used at Johns Hopkins. A modified RPP program was posted in September 2008, which states:

“The Johns Hopkins Hospital provides Respiratory Protection Devices (i.e., Powered Air Purifying Respirators (PAPRs) or Suitable Alternatives) for use by staff who have patient care/environmental responsibilities for patients on airborne precautions or patients who are receiving Ribovirin, for the protection of all staff, prevention of disease transmission, and to comply with external regulatory agency requirements.

“PAPRs are battery-powered systems that use a small HEPA filter unit to clean ambient air before it is delivered to the wearer. A PAPR system typically includes a blower/filter unit/battery pack (base unit), a headpiece, and a breathing tube that connects the base unit to the headpiece. Suitable alternative devices include N95 Respirators. While this policy refers primarily to PAPRs, it should be understood that suitable alternative devices may also be employed, based on the approval of HSE (Health, Safety, and Environment).”

It goes on to state that “The PAPR is the primary device available for use. N-95’s are used by staff who cannot use the PAPR for any reason.”

This proposed regulation is considerably more limited in requiring PAPR use than is the Johns Hopkins policy. PAPRs would not be required under the proposed standard for entry into airborne infection isolation rooms, for example. They are only required for the performance of high hazard procedures on AirID cases or suspected cases. Where this use would interfere in the performance of the task or tasks, a PAPR is not required by the proposed standard.

Please see response to comment #AF1 for further discussion of PAPRs.

Paul A. Schulte, Ph.D., Director, Education and Information Division, National Institute for Occupational Safety and Health, by letter dated August 14, 2008.

Comment #PS1: The commenter stated that the reference in the public notice to a planned NIOSH study concerning respirator fit-test intervals is potentially misleading. “The study is not designed to establish a scientifically validated periodicity for fit-testing of respirators. The study

is designed to track changes in test subjects' key facial dimensions and fit factors with designated respirator models and sizes at 6-month intervals over 3 years. NIOSH expects the data gathered in this study will provide insight into: (1) which facial dimension changes correlate with changes in respirator-to-face fit factors, and (2) the rate at which various key facial dimension vary over times. These detailed analyses will **not** support a scientifically based evaluation of the effectiveness of annual fit testing."

Response: The Board thanks Dr. Schulte for providing this information. Len Welsh, Chief of the Division of Occupational Safety and Health, wrote to Dr. Schulte to request clarification of these comments (see Welsh letter dated 28 August 2008).

On October 17, 2008, Mr. Welsh received a response from Dr. Schulte, dated October 15, 2008. In this letter, Dr. Schulte stated that "On behalf of NIOSH, I would like to offer a clarification of the information you reference and an update on the status of the NIOSH study. Dr. Schulte explained that the NIOSH study cited has been "critically reviewed and significantly revised since the report by John Decker at your December 8, 2005 advisory meeting. The protocol and study objectives have undergone significant changes during the past three years of development, and the project has not been initiated."

The inclusion of the correspondence between Dr. Shulte and Len Welsh in this record is intended to clarify the status of NIOSH research.

The Board believes there is still adequate reason to propose a date of January 1, 2014, for the termination of the exception permitting biennial fit-testing of some respirator users.

Response to Comments from Board Member Jonathan Frisch received at the August 21, 2008, Public Hearing:

Comment #JF1: In regards to subsection (g)(5) and Appendix B, that he would appreciate more information regarding why an alternative respirator questionnaire is necessary.

Response: In the course of the July 26, 2004, advisory meeting, several participants identified significant problems in the completion and review of the respirator questionnaire contained in Section 5144, Appendix C. Participants agreed that many of these questions would not be used by physicians and other licensed health care professionals (PLHCP) in determining whether an employee can use a filtering facepiece respirator or PAPR in typical health care operations. Some participants reported that some employees objected to the detailed history questions (in the form of "have you ever had...") as invasive of their privacy and objected to furnishing this information, since they did not perceive it as being directly relevant to their use of respirators in their current employment. Participants also indicated that having to re-do respirator medical evaluations using the questionnaire in Section 5144 Appendix C was creating a problem in meeting the implementation date of the section.

As a result, the Board adopted an emergency regulation on September 23, 2004, permitting the use of medical evaluations conducted prior to October 18, 2004, for filtering facepiece respirators used to protect employees against tuberculosis. On January 20, 2005, the Board adopted a permanent regulation to this effect. The questionnaires used in these evaluations were broadly used in health care and addressed the subjects in Section 5144, Appendix C.

Advisory meeting participants supported developing a questionnaire that would specifically address the questions that would prompt a further evaluation by a PLHCP. Several occupational health physicians, including physicians from the California Department of Health Services, reviewed the existing questions and forms, and determined that the content of proposed Appendix B was appropriate for assessing the ability of employees to use respirators in this context, and provided a medical screening equivalent to the screening provided by the questionnaire in Section 5144, Appendix C.

Finally, it should be mentioned that the evaluating PLHCP will have the final word on whether the information gathered by Appendix B is sufficient for them to make a determination regarding the individual employee's ability to use a respirator. The PLHCP or the employer can still choose to use the questionnaire in Section 5144, Appendix C.

Comment #JF2: In regards to the exception to annual fit-test requirements proposed to subsection (g)(6)(B)3, Dr. Frisch asked if the Division could do anything to increase the protection provided to employees whose employers utilized the exception to provide biennial fit-tests instead of annual.

Response: An additional safeguard has been included to ensure that employees are provided with a good-fitting respirator. Both existing Section 5144, and proposed Section 5199 require additional fit-tests when an employee reports having certain facial changes such as surgery, dental work, or significant weight changes, and if an employee reports that he or she needs an additional fit test.

Mary Mendelsohn, of the Association of Professionals in Infection Control (APIC) worked with the California Hospital Association to survey hospitals in California and determine how many employees changed respirators as a result of an annual re-fit test. She found the number of employees needing a different respirator to be very low, and also found that a significant number of them would be predicted based on their answers to questions regarding facial changes. (See response to comment #BK18 and Mendelsohn letter)

For this reason, the proposal now includes Appendix G, which would be mandated for employees who are not provided an annual fit-test. This appendix contains respirator fit-test screening information, and asks whether there have been weight or facial changes, and also asks whether the employee is requesting an additional fit-test, even if the employee does not report weight or facial changes.

The Division believes that this Appendix provides an appropriate reminder to employees regarding the need for a respirator to fit them, and a means to detect those individuals who are in need of an additional fit-test.

Comment #JF3: Dr. Frisch asked if the Division could provide evidence supporting the use of N95 respirators against infectious aerosols.

Response: In 1995 NIOSH published a final rule that specifically identified N95 respirators as being appropriate for use against tuberculosis (60 FR 30335). This rulemaking was based on a significant record, including many scientific studies. NIOSH is the agency that has the primary

responsibility for approving respirators, and OSHA and Cal/OSHA rules (29 CFR 1910.134, 8 CCR 5144) reference NIOSH approvals. Since that time there have been a number of studies addressing the appropriate assigned protection factors for N95 filtering facepiece respirators and their effectiveness against infectious aerosols. Qian et al, for example reported that N95 materials were very effective against aerosols in the size range of concern (Qian, 1998). Although the specific numbers have varied, it has generally been found that fit-tested N95 respirators provide a 5th percentile protection typically around 10, and always greater than five. For example, a recent NIOSH study (Duling, 2007) tested 15 models of N95 filtering facepiece respirators, 15 models of elastomeric facepiece respirators with N95 particle filters, and six models of surgical masks. All 15 models of N95 filtering facepiece respirators provided a simulated workplace protection factor 5th percentile value over 10 when the respirator had passed a fit-test using saccharine or the PortaCount Plus. Passing a fit-test using Bitrex did predict a lower 5th percentile value averaging 7.9.

The studies cited by Bill Kojola and other commenters (Lee, 2008, Balazy, 2006, and Eninger, 2008) raise concerns about whether some users will realize a protection factor of 10 in regards to certain particle sizes, with some N95 respirators. However, even the worst performing N95 respirator provided a 5th percentile APF greater than 5 for all particle sizes. The better performing N95 respirators provided a 5th percentile APF greater than 8 for all particle sizes, and the 25th percentile was considerably greater than 10. This study, if confirmed by other data, may indicate a need for NIOSH to amend the test procedures in 42 CFR Part 84, but the results of this study also clearly indicate that N95 respirators reduce risk to virtually all users.

A study of SARS among 43 critical care nurses in Toronto who were exposed to SARS patients found that 2 out of 16 nurses who consistently used N95 respirators contracted infection, as compared to 5/9 who used them inconsistently, yielding a relative risk of 0.22, p=0.06 (Loeb). This indicates that N95 use was protective. In addition, the activities that were found to be at highest risk (intubation and suctioning before intubation) require a higher level of respiratory protection under this proposal.

A different but related issue is that the concept of “assigned protection factor” was developed in relation to chemical risk. For chemical exposures for which there is a threshold (non-carcinogens) the concept is that an exposure limit is determined, including some safety factor. The assigned protection factor then determines the maximum concentration in which the respirator can be used by multiplying the exposure limit by the assigned protection factor. (This is a simplification, and does not include issues such as cartridge capacity, etc.) Infectious aerosols differ, because for at least some pathogens, such as tuberculosis, the infectious dose may be contained in one droplet nuclei, and therefore, respirators and other controls are directed at reducing the risk that an infectious particle will be inhaled and deposited in a manner that will result in infection. One determinant of this risk is the protection factor of the respirator, but if the permitted dose is one pathogen containing droplet nuclei, there is no finite protection factor that will provide 100% protection if there are pathogens in the environment.

Comment #JF4: Dr. Frisch expressed a need to include non-medical home care in the standard.

Response: The issue of non-medical home care was discussed at advisory meetings. Neither meeting participants nor Division staff were able to discover evidence related to the risk of non-

medical home care employees. These activities are similar to activities performed in assisted care living facilities, which are also not included in the standard.

The occupation of non-medical home care is undergoing considerable change and restructuring, such as the creation of In Home Support Services public agencies. The Division staff will continue to monitor this situation. In the mean time, employers who come within the scope of the Cal/OSHA authority are required to assess infectious disease risks in accordance with the Injury and Illness Prevention Program. For further discussion, please see response to comment #MC2.

Comment #JF5: Dr. Frisch was concerned about the exclusion of dental offices.

Response: The dental office exclusion is based on infection control guidelines in dental offices, published by the Centers for Disease Control and Prevention, and on the practical difficulties of performing procedures on patients with aerosol transmissible diseases. However, in response to comments from Dr. Frisch as well as public comments, the proposal now specifically requires employers to include the screening and employee training procedures in the IIPP, and also requires a physician to determine that a screened patient does not have an ATD prior to performing procedures. Unlike health care workers, dental workers are also not considered at increased risk for tuberculosis.

Comment #JF6: Dr. Frisch stated that the standard should include a requirement for cleaning and disinfection of the worksite for referring employers.

Response: A sentence containing this requirement has been added to subsection (c)(1).

Comment #JF7: Dr. Frisch stated that he is concerned that subsection (a)(1)(c) is not sufficiently specific about what is meant by police services. He is also concerned that the standard provide a consistent level of safety for police officers across the state, and not be swayed by individual departments that may have a stronger program than others.

Response: The language of subsection (a)(1)(C) has been modified to specifically address that the services covered are those that are provided during transport or detention of persons reasonably anticipated to be cases or suspected cases of aerosol transmissible diseases, and those services that are provided in conjunction with health care and public health operations. This is consistent with public health recommendations and the recommendations of participants in advisory meetings. Many departments currently provide N95 respirators for use by officers when there is a concern about tuberculosis or other airborne disease. The use of particulate respirators to protect against infectious diseases is included in the Model Respiratory Protection Program provided by the Commission on Police Officer Standards and Training (POST), which is a statewide reference, and was developed in cooperation with the Division. The Division intends to continue to work with local and state law enforcement in implementing this standard.

Comment #JF8: Dr. Frisch asked if there is there a way for this standard to apply to volunteer workers.

Response: Len Welsh addressed the jurisdictional issue during the course of the hearing to the effect that the Division has no jurisdiction over people who are actually volunteers in health care facilities, although there are many details involved in determining that status. As a practical

matter, most health care institutions require that volunteer workers observe the same infection control procedures as paid workers, because that is necessary to prevent health care associated infections.

Comment #JF9: Dr. Frisch stated that the standard should address computer-based training and other training modalities.

Response: Language was added in subsection (c) and subsection (i) to address training that is not provided in person.

Comment #JF10: Dr. Frisch expressed concern about whether the communication requirements regarding the “hand-off” of patients are clear.

Response: Each employer is required to develop effective procedures for communicating with other employers regarding the infectious disease status of referred patients, and to establish a means to receive information as well. This issue was discussed at length in the advisory process. For example, it was suggested at one meeting that a sign be placed in the home of an ATD patient to inform home health workers or emergency responders that there was a case or suspected ATD case in the house. This idea was rejected for a number of reasons including confidentiality and social stigmatization. Also, different types of employers will have different information to send and receive. The Division intends to provide guidance during the roll-out of this standard that will be more specific to different types of work operations.

Comment #JF11: Dr. Frisch said that the standard should clarify that a PLHCP cannot medically remove himself/herself.

Response: There are two types of conditions in which a PLHCP would recommend precautionary removal – (1) as a result of a medical evaluation due to a TB test conversion, or (2) as a result of a medical evaluation after an exposure incident. In both cases, the employer is choosing the medical provider who will evaluate the employee. The standard does provide that when an employer is acting as the evaluating health care professional, that the employee be informed that it can refuse to consent to receive medical services from the employer-health care provider. In that case, the employer must make arrangements for the employee to see another PLHCP. However, in no case does the standard permit a PLHCP to determine, in the absence of one of the triggering condition and an employer referral, that the PLHCP himself or herself should be medically removed. The only exception is for a self-employed PLHCP, as the Division has no jurisdiction over self-employed persons.

Comment #JF12: Dr. Frisch recommended that the standard address influenza during the shoulder months (the months immediately adjacent to the generally recognized influenza season).

Response: There are two references in the proposal to the influenza season. The first is in subsection (c)(3)(B) which requires the referral of patients who exhibit influenza-like symptoms outside of the months typically associated with seasonal influenza (November through February). As a result of this comment and others, a modification has been proposed to add a sentence clarifying that a client or patient exhibiting influenza-like symptoms for a period greater than two weeks should also be referred.

The second reference is to provision of influenza vaccine, in subsection (h)(10). The exception states that an employer need not provide the seasonal influenza vaccine outside of the period recommended by the CDC. This exception is triggered by the recognized season for administering influenza vaccine, which typically starts around September and ends in January or earlier. However, in any given year, this exception is flexible in terms of being based on the CDC recommended period for providing influenza vaccine.

Comment #JF13: Dr. Frisch expressed concerns about the costs to state agencies as discussed in the comments submitted by the California Department of Corrections and Rehabilitation (CDCR).

Response: Please see response to comment #BRK1 for discussion of CDCR costs.

Comment #JF14: Dr. Frisch expressed discomfort with the proposal's lack of a specific set of documents to be used as the threshold for adding covered diseases, pathogens or vaccinations to be included in the proposal rather than any CDC or CDPH recommendation. Recommendations can take a variety of forms, and he expressed concern that the proposal should be more precise about what sort of notice is expected to be considered for adding diseases, pathogens or vaccinations to the lists in the Appendices.

Response: The list of diseases triggering inclusion in the standard is in Appendix A. Pathogens required to be addressed by a risk assessment are included in Appendix D. Similarly, the list of vaccinations required for health care workers is defined in Appendix E. Other than novel and unknown pathogens, such as SARS in 2002-2003, the list in Appendix A will only change through rulemaking. The list of reportable diseases is promulgated by the CDPH into Title 17, California Code of Regulations, under authority of the Health and Safety Code. Therefore notice will be provided to the public of additions of reportable diseases. Similarly, the list of Aerosol Transmissible Pathogens – Laboratory (appendix D) and required vaccinations (Appendix E) will only change through rulemaking.

A modification is proposed to subsection (b) and other subsections, defining a term “public health guidelines” and listing current versions of guidelines to be incorporated by reference, including a comprehensive list of tuberculosis guidelines issued by the California Tuberculosis Controllers Association and the CDPH, and the national reference for vaccine preventable diseases published by the CDC. For new diseases, or diseases not addressed in these guidelines, the proposed standard will rely on the recommendations issued by the local health officer and the CDPH based on their authority in Title 17. The Division will monitor newly issued guidelines and propose rulemaking to update referenced guidelines for medical services including the vaccinations listed in Appendix E. The Division will also propose rulemaking if it is necessary to add or remove diseases or pathogens from Appendix A or D.